PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: ABREU

Atty. Docket No.: P66081US1

Serial No.: 09/778,762

Group Art Unit: 3626

Filed: February 8, 2001

Examiner: Lena Najarian

For: SYSTEM AND METHOD FOR COMMUNICATING PRODUCT RECALL INFORMATION, PRODUCT WARNINGS OR OTHER PRODUCT-RELATED INFORMATION TO USERS OF PRODUCTS

DECLARATION UNDER 37 C.F.R. §1.131

I, Marcio Marc Abreu, hereby declare as follows:

1. I am the inventor of the subject matter of the captioned application, residing at 72 Highland Park Road, North Haven, Connecticut 06473.

2. I have reviewed the Office Action of June 13, 2006, and in particular the citation of U.S. Patent Application Publication No. 2001/0053980 to Suliman, Jr. et al.

3. Suliman, Jr. et al. was published on December 20, 2001, based upon U.S. Patent Application Serial No. 09/738,664, filed December 15, 2000. The '664 application claims the benefit of the filing date of provisional patent application

No. 60/172,351 filed on December 16, 1999. It is therefore my understanding that the Suliman, Jr. reference has an effective date of December 16, 1999.

4. The captioned application has a filing date of February 8, 2001, and claims the benefit of provisional patent application No. 60/182,000, filed February 11, 2000.

5. Prior to the filing of my provisional patent application, Serial No. 60/182,000, I prepared several drafts of the provisional patent application prior to its filing on February 11, 2000.

6. Attached is one such draft of the provisional patent application. On page 67 of the draft application, I included the notation "PAREI AQUI 8-1-99", which translates from Portuguese to "stopped here" with the date of August 1, 1999. The draft application includes support for the claimed subject matter of the captioned application.

7. I invented the subject matter claimed in the subject matter claimed in the captioned application at least as early as August 1, 1999.

8. The attached draft patent application establishes that I had invented the subject matter claimed in the captioned application prior to the effective filing date of December 16, 1999, for the Suliman, Jr. reference.

9. It is therefore respectfully requested that the rejections made in view of the Suliman, Jr. reference be withdrawn and in the absence of prior art, allow the captioned application to issue as a patent.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that the statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Marcio Marc Abreu

May 8th, 2007

APPARATUS AND METHODS FOR ELECTRONIC LOCATION, COMMUNICATION, AND INFORMATION SYSTEMS

FIELD OF THE INVENTION

The present invention relates to a product-based system consisting of an automated electronic and network-based recall and information system to assist the user in timely identifying a health hazard or any other hazardous situation or insults due to unintended harmful effects and adverse consequences of a variety of products as well as to prevent the occurrence of said harmful effects and to prevent the spread and continuation of said harmful effects, in particular to track, identify and locate dangerous products as well as the adverse reactions and adverse effects of drugs, medical devices, food, cosmetics and other consumer products allowing the user to take appropriate action and preventive measures in regards to the potential hazardous situation, and in particular by being able to privately, timely, individually and cost-efficiently locate and alert the user at risk and to provide guidelines to assist said user before any insult, damage or injury occurs using a hand-held device with data entered preferably using bar-code technology associated with a computer based system in which the information on harmful products is continuously updated by recall and information sources and automatically transmitted over a public network as the internet **preferably using a user-server computer systems in which a server receives, retrieves, store and send the information on recalled products to a user identified as using said recalled product and the server stores the information for later retransmissions to other users which enter data as user of said recalled product.**

BACKGROUND

The world and in particular the United States face challenging health care cost with a grim picture of rapidly rising health care expenditure with a rapid increase in the number and spread of preventable illnesses and injury due to the unintended harmful effect of a variety of products. According to the projections by the Health Care Financing Administration of the United States Department of Health and Human Services, health care spending as a share of US gross domestic product (GDP) is estimated to increase from 13 percent to potentially and amazingly close to 20% of the United States GDP after the year 2000, which clearly demonstrates how unwise health care spending can affect the overall economy of a nation. The United States Department of Agriculture estimates medical costs with illness caused by the unintended harmful effect of food alone to amount to over 34 billion dollars in 1998. It is easy to see how threatening to the economy of a nation such situation is if one combines the total 1998 revenues of Coca-Cola and Microsoft and finds out that the above medical costs due to the unintended harmful effect of food astonishingly surpasses the combined global revenues of such giant corporations. The actual picture is unbelievably far more critical since the above medical cost is only a fraction of the total medical cost created by the unintended harmful effect of products. The situation is much more serious and inconceivably far more costly, when the harmful effects of drugs and other consumer products are accounted for, ultimately creating an unfortunate tremendous unthinkable burden on the income tax payer and average worker who at the end is the one paying for the vast majority of the cost of health care services. The fastest and most effective way to protect the public from an unsafe product and thus decrease such outrageous and unwise medical expenditure is by timely and reliably identifying, locating and instructing the user of such unsafe products. Due to seriousness and vastly increased number of harm and death caused by variety of products, the government, private enterprises and medical organizations have an urgency in finding means and technology to prevent the spread and occurrence of illness and injury which invariably occurs due to the lack of identification, location, and treatment of the user of the harmful product, with such means and technology being critical for the containment of the acceleration in health care

spending.

The development and use of a variety of medications (drugs) are essential to promoting health and treating a great number of disorders while substantially increasing life expectancy. A notorious example of the benefits of drug discovery can be easily observed with the development of a variety of antibiotics which have saved millions and millions of lives, and antihypertensive drugs which by controlling high blood pressure helped to reduce the rate of strokes and heart disease. The use of cholesterol lowering agents have helped decrease the mortality by heart disease, the use of anti-depressants have helped millions of individuals to better enjoy life, and the use of anti-glaucoma medications helped millions of patients to preserve their sight. The exhaustive process and laborious research involved with drug development have created many other breakthroughs and formidable drug discoveries leading to the control of previously untreatable diseases and decrease in morbidity while enhancing the quality of life and increasing life expectancy for millions of people across the world. However, these great benefits are associated with serious and costly problems due to the astonishing fact that not only thousands, but actually hundreds of thousands of patients die every year in the United States alone as a result of drug reaction or unexpected and unintended adverse effects and reactions caused by prescription drugs.

Adverse drug reactions alone, consisting of correctly administered FDA-approved drugs, are responsible for the shocking figure of over 106,000 deaths per year in the United States alone. Adverse drug reactions are the fourth leading cause of death in the United States; right after heart disease, cancer, and stroke. The number of deaths caused by the harmful unintended effects of prescription drugs is amazingly more than the annual totals for AIDS, suicide, and homicide combined and more than twice the deaths due to accidents which is around 40,000 a year. A person is more likely to die from adverse effect due to prescription medication than from accidents, diabetes, or lung disease. The staggering number of close to 300 deaths per day due to prescription drug adverse reactions remains unchanged due to the difficulties in the timely identification, location, prevention and treatment of individuals at risk. Besides fatal events, there are over 2.2 million annual non-fatal but serious reactions, and millions of complications and disabilities related to unexpected effects of drugs, chemical compounds and a variety of products which are responsible for some of the staggering health care spending that we face today. Unfortunately, this alarming picture will continue to worsen in the future with its devastating consequences to the economy, tax-payer and society as a whole if appropriate measures for prevention and the timely identification and location of the harmful products and affected individuals is not instituted avoiding spreading of potentially preventable injuries and disease.

The above catastrophic picture is even more grim and astonishing since the above figures exclude drugs which were misprescribed or used wrongly as well as drug abuse and drug overdose and adverse effects caused by non-prescription drugs (over-the-counter medications), devices and chemical compounds which are injected, ingested, or placed in or on the human body. If the adverse effects and fatal reactions related to the use of over-the-counter drugs (non-prescription drugs) and other products such as cosmetics were included the numbers would prove to be even more staggering. The risks, injury, and death caused by unintended adverse drug reactions and defective products could be substantially reduced if appropriate technology were used such as found with the methods and apparatus of the invention.

The misuse of prescription and non-prescription drugs due to the inability to understand or identify a potential hazardous effect, has not been accounted in the above numbers either, but are also a critical cause of morbidity and mortality related to the utilization of a variety of products, devices, and chemical compounds. The ability to understand information about drugs, chemical

compounds or devices is central to the prevention of some of the above devastating consequences. The U.S. Department of Education estimated that 47% of all adult Americans had poor reading and comprehension skills and large amounts of medical material exceeds the reading abilities of most of the American adult population. Although, there is information printed on the package and product insert of prescription and over-the-counter drugs as well as many other products, the majority of the population has difficulty to understand, interpret, or use the information provided. As a result, many individuals suffer adverse effects due to the inability of understanding the content of the information provided by the manufacturer and its relationship to his/hers individual health status. It is important to remember that the health status of an individual is a dynamic process with continuous change over time, with said changes in the health status capable of potentially interacting with chemical compounds and devices used by the patient causing serious and even fatal effects and reactions. New technology is surely needed that will assist the user in safely using a drug despite their knowledge of medical terminology and interaction of drugs with the human body's continuously changing biological variables.

The prior art has provided important home-testing technologies such as the devices by Abreu in which patients can self-administer measurements of eye pressure and perform a complete non-invasive blood analysis with evaluation of a variety of biological variables. The combination of home-testing devices by Abreu with the methods and apparatus of the invention allow a complete prevention system in regards to interaction of chemical compounds used by the patient and changing biological variables. A brief example demonstrates the situation. Patients using some medications for common cold or flu or products containing steroids may be at risk for damaging their eyes or even blindness if one biological variable, in this case, eye pressure is significantly increased. The increase in eye pressure can be silent without any symptoms which may indicate that said individual may have glaucoma. The packet insert of the common cold pill and some steroid drugs may have a warning for not using said medication if you have glaucoma. Unfortunately, the patient taking the pills, most of the time, does not know what glaucoma means, even after reading the packet insert, and will continue to use the drug not knowing that is at risk of eye damage. The system of the invention will alert patients about said risk regardless of the patient's knowledge of the meaning of the medical terminology in the packet insert or their health status.

The fast rising of health care costs also relates to the disturbing fact that millions of patients suffer from severe complications, permanent disability, and death as a result of untimely identification of a health problem or untimely arrival at the medical provider or hospital and the seriousness and medical cost of this situation of untimely treatment cannot be overstated. The system of the invention besides preventing the harmful event from occurring as above, it will also alert the user to seek treatment and arrange for treatment for the situations in which there is need for such treatment due to injury or illness caused by a harmful product.

The majority of adverse effects and reactions due to the use of chemical compounds and/or devices occur after said chemical compounds or devices are already in the marketplace and being used by potentially millions of patients. The pre-marketing trials for evaluation of drugs and devices frequently do not have sufficient power to reliably detect adverse effects and reactions and lack the length of follow-up which is needed to evaluate the delayed consequences present with chronic use or wide spread administration of drugs and devices. Besides the above limitations with pre-marketing evaluation by the United States Food and Drug Administration (FDA) of drugs and devices, these trials do not include interaction of drugs with a variety of biological variables as well as the use by special population who could be at higher risk for adverse effects or reactions compared with the general population. Furthermore, the inability to identify the changes that occur in the healthy status of an individual such as changes in blood

pressure, eye pressure, blood glucose, blood cholesterol, weight, and the like, make it virtually impossible to identify and prevent adverse reactions or effects that occur with the utilization of drugs and/or devices interacting with changing biological variables. Most important is the fact that there is no art that is directed or capable of identifying and locating the individual user of the harmful product.

In order to identify and thus prevent the catastrophic complications due to the adverse effects of drugs, chemical compounds and devices which were not ascertained during pre-marketing evaluation, a post-marketing surveillance system has been instituted by the FDA. The sample size of pre-marketing trial is small with a short follow-up when compared with the use of the drug by the general population in which thousands and even millions of patients will use the drug or devices for a long period of time with the consequent development of drug reactions. The post-marketing surveillance system relies on the spontaneous reporting by health care providers and companies of adverse effects or reactions which were identified with the use of the chemical compounds, devices, cosmetics, or the like. However, the post-marketing surveillance does not have any means to alert the patients at risk, the system relies basically on the physician informing patients on an individual basis which is done at the doctor's discretion and available resources. The post-marketing surveillance has primarily the objective of alerting the health care provider and companies, but no system is in effect to directly address the user of the product.

The adverse events or reactions with the use of drugs, devices, cosmetics, or the like can occur in different stages: shortly after initiation of use, and commonly with long term use, but most important and critical are adverse effects that occur remotely even after the drug, chemical compound or device has been discontinued and/or recalled. Moreover, for each one report received by the FDA, there are over 100 actual reactions occurring which shows that the post-marketing surveillance reporting system used by health care providers substantially underestimates the actual number of adverse reactions and effects. Unfortunately, the most frequent way that patients find out that a product is harmful is after they suffered injury or even death caused by the product.

Besides the unintended detrimental effects caused by drugs and/or devices, the use of medications or devices may be associated with unintended beneficial effects. The post-marketing surveillance system also attempts to identify those beneficial effects and was key in identifying that hormonal therapy in post-menopausal women reduces death from cardiovascular disease, and that oral contraceptive users have a lower risk of ovarian cancer. However, there are no means or systems in the prior art that privately and individually informs all of the users of a beneficial effect related to the drug they are using.

The post-marketing surveillance system and prior art currently used suffer from many limitations and drawbacks, and is unable to efficiently identify, locate, prevent, and treat the unintended harmful effects of a variety of products after the product has been identified as harmful as the above figures clearly showed and some of the following examples will further demonstrate. A widely TV advertised drug by the name Loratadine which is used to treat allergies, during post-marketing surveillance, was found to cause esophagus rupture with even potential fatal complications. The most unexpected and amazing reason for that was identified as the size of the tablet for a particular formulation with a tablet that was too large which caused blockage and subsequent potential rupture of the gastrointestinal tract with the caustic gastrointestinal contents being poured into the mediastinum and the surface of the heart leading to the demise of the patient. Although, there was a great effort by the government and manufacturer to notify doctors and patients about this catastrophic event, most patients do not have any means to know the new and completely unexpected complication caused by that particular formulation of Loratadine

unless informed by their doctors or in rare occasions through the media. Due to the widespread use of this drug and the obvious difficulties in locating and alerting patients with the prior art, astonishingly even after the announcement to doctors and the public by the FDA and the manufacturer about these devastating complications, patients unfortunately still were using the drug due to the lack of knowledge of the potential complication hidden in the size of the tablet. Another similar situation occurred with the antihistaminic drug called Terfenadine, which was found later on to cause potentially fatal arrhythmias when taken with certain antibiotics. In many cases, even after a drug has been discontinued and/ or recalled, patients still use the recalled drug and are injured because it is virtually impossible for doctors, companies, and even the government to locate and inform all of the patients using a particular drug of the complications related to that drug. Drugs used by patients are usually written on patients' charts and it would be necessary to manually review the thousands of charts for every medical practitioner and subsequently identify written information on the chart regarding different medications used by each patient. Since in most cases there is no indication about the date that a certain patient was started on a particular medication, this chart review would have to include the hundreds of pages that each chart may have. Of course this would have to be done any time a new adverse effect was identified. Naturally, this is an insurmountable task and the data impossible to be realistically retrieved with each patient identified, located, and warned about the potential hazardous situation. Sometimes the product does not need a prescription which makes the identification and location of the user virtually impossible with current means and prior art. The real example involves a shampoo to treat dandruff which was later found to cause fatal reactions, blindness, diabetes, and other severe complications due to some of the ingredients present in its composition. Since this product was being sold over the counter without the need for a prescription there is no way to identify who is using this extremely dangerous shampoo which has been recalled and removed from the market. However, users continue to perish and suffer since they did not have access to the information. Very unfortunately, currently the most common way the user finds out about the potential harmful effects by certain products is after suffering the illness, injury or death caused by said harmful product. The above are few real events that occurred with those products, but there are millions of products causing harm and being recalled every year.

The picture is unfortunately more shocking and alarming when we consider the fact that defective products cause a similar amount of injury as described above, an even deaths as the following example will show. On May 12, 1998, Daniel Keysar, a 17-month-old toddler died when his portable crib collapsed and strangled him at his licensed day-care facility in Chicago. The loss of a young child is surely irreparable, but more difficult to accept is the fact that it could have been prevented. Astonishingly the portable crib that killed the young child had been recalled in 1993, five years earlier, by the United States Consumer Product Safety Commission (CPSC) and by the manufacturer, but the parents never had access to that information. The crib collapsed wedging the toddler's neck inside the folded V of the rails and killing the child in one of the most horrifying ways, the inability to breath, by slow suffocation preventing the child from breathing and even to cry for help during the last minutes of his life. This same type of crib had already strangled and killed many children, but the prior art and systems available are completely inefficient and absolutely limited in their ability to track, identify, locate, and alert the user about a potentially harmful and even deadly product. Although the recall was done several times, primarily through the news media, adds and other conventional printed means, the message reached a very limited amount of the population and even today this deadly product is still present in many homes. It is important to remember that strangulation if not fatal, leads in many cases to brain damage with the consequent lifetime of nursing and institutional care for those unfortunate toddlers with the obvious resulting increase in health care spending and the priceless emotional

cost of lost lives as occurred with Danny Lineweaver who died at age 11, after sustained brain damage at age 2 in a similar crib.

The following illustration will further demonstrate the inefficiency of the prior art in relation to recalling, tracking, and locating already known harmful drugs and consumer products. Within weeks of the killing of Daniel Keysar, his parents begin an urgent and massive e-mail campaign "Prevent death of next child" warning of the danger of the recalled portable cribs with the message being forwarded all over the US and the world. Daniel's parents founded Kids In Danger, a charitable organization that warned millions of people in the US and abroad about the dangers of recalled juvenile products by granting interviews to print, radio and television media and through Email and printed warnings Campaign. The message reached various organizations such as American Academy of Pediatrics and other Medical and public organizations. Many of the responders had a recalled crib but were not aware of the danger. Some of the responses to the e-mail posted by Kids in Danger demonstrates the magnitude of this alarming problem: 1). "The dissemination of recall information is horribly lacking. We have called all of the manufacturers of the equipment we use with our children and discovered that the carrier of our stroller has been recalled because it flips children out of the seat; we returned the warranty card over a year ago, when we purchased the stroller, and still were not notified of the recall. It is certainly clear now that parents and child care providers and state agencies need to be proactive in chasing this information down" 2). "I think it's bad that we have to really research in order to find out if a product we bought is considered safe. That safety seems to be an ever-changing line, does it not? I grieve with the families that have suffered tragedies it is senseless" 3). "I read the newspaper every day. I never heard about this danger to my children until now."

This outstanding organization, Kids in Danger, issues a press release urging a far-reaching advertising campaign and begins a nationwide television and print media campaign and also distributed public safety announcements to radio stations nationwide, encouraging consumers to call the CPSC to verify whether products in their possession have been recalled for safety problems. The massive nationwide and international e-mail campaign as well as massive media announcement, associated with extensive government actions that occurred after the death of Dainel Keysar action are important and helpful, but unfortunately inefficient and limited as all of the prior art. Even after all of those efforts the same needless tragedy happened again, and on August 19, 1998, 3 months later after the death of Daniel Keysar, another innocent baby is killed by the same product, William Curran, a 10-month-old baby from Fair Haven, New Jersey, is killed in the same terrifying manner strangled to death when the same model of portable recalled crib collapsed and crushed his throat. Unfortunately the life-saving information about the deadly recalled crib never reached this innocent child. It is clear that the prior art suffers from severe limitations for effective recalling and location of harmful products and the users of said harmful products.

In the last words of Daniel's mother, Linda, to his son one can also experience the depth and extent of the permanent damage and real life drama caused by the lack of means to timely and efficiently track and locate harmful products. Excerpt from the Chicago Magazine November 1998: She spoke to him. She told him she was sorry he would never get to grow up, that he wouldn't get to see his brother, Ely, again, and on and on, until the nurse finally interrupted. "You can hold him as long as you like," she said, "but soon you'll need to say goodbye." Linda hadn't thought about that. The heat lamp had done its job for a while, but now Danny's body was growing cold and hard, and his fingernails and lips were turning blue. She would have to say goodbye. So Linda wrapped him back up in the blanket. The nurse cut a lock of Danny's hair and gave it to her. "That was his first haircut," she told the nurse. And she cried.

Interestingly state inspectors had visited the day-care a week before Danny's death and the daycare center's manager also had no idea the crib had been recalled. I must attest that my own son also used one of those recalled cribs for a very brief period of time. As a result of Danny's death in a licensed day-care home in Chicago, the Mayor announces a recall initiative for the City. The most amazing fact is that of the 1.5 million recalled portable cribs and play yards, only about 15% were accounted for (Chicago Tribune, June, 1998.) Thus, over 1.2 million defective cribs remain in circulation, showing the inefficiency and limitations of the prior art and recall system. According to Consumer Reports 99Buying guide "the odds of your hearing about an unsafe product are slim. Manufacturers are reluctant to issue a recall in the first place because they can be costly. And getting the word out to consumers can be haphazard." As kids in Danger states The only way to be certain that you are not using a recalled product is to check for yourself a**nd Periodically check with these government and private agencies about new recalls. Unfortunately there is no prior art that actively searches and notifies individually and privately the user for all of the unique products such user utilizes and informs the user about warnings/recalls for all the products being used by said individual user.** There are also web-sites that send undiscriminating and random recall information for virtually all recalled products, but is obviously impossible and absolute inappropriate to send randomly thousands of e-mail every day for each user with said user having to waste an incredible amount of time every day to sort through all of the thousands of daily messages received in order to identify a potential harmful product said user is using, but even if the user identifies among the thousands of daily messages the name of one product being used, said user would have to know if that particular product being used came from the plan or lot or section or processing area that corresponds to the product being recalled, and then said user would have to check each package individually to try to find out if said user has a recalled product. There is no prior art that can individually inform an user about a recalled product according to precise identification characteristics of the product such as processing plan, section, and so forth. Since it is not possible or even appropriate to send thousands of daily messages to each of the millions of users, the prior art selects and send one message randomly to the user showing the obvious incredible limitation and drawback of such prior art in order to alert the user of the harmful product. Very unfortunately, the individual user cannot afford the incredible time, effort, and expense needed to sort through the millions of recalled products to find out which products being used were actually previously recalled and to seek for warning information for each and every product being used. Moreover, the user does not want to be inundated with the millions of recalls and warnings which do not correspond to the products being used by said user. Furthermore, this indiscriminate e-mailing is completely unlikely to reach the user of a harmful product in a timely fashion, as occurred with the deadly crib and the tragedy repeated itself. In all of the prior art the system is user-based in which the user has ultimately to actively search for the recall and warning information about the products being used, rather than product-based in which each and every product information actively search for all of the individual users of a particular product and the specific user of the unique product passively waits for the information on said used products to reach said user as soon as said information is available. The system of the invention as will be described later creates a new driver system consisting of a product-based system as partially described above.

In 1998 alone, the CPSC recalled more than 38 million individual units concerning harmful children's products, but because most people never hear about these recalls, the majority of said harmful products are still being used. CPSC usually relies on the media, printed material and manufacturers to recall harmful products voluntarily and most of the manufacturers cooperated, but even that doesn't guarantee effective results. During the past decade, 622 children have died

in defective cribs, a rate of 57 children each year and at least 137,000 children were hurt which translates in almost 400 children injured a day. CPSC uses various means to inform the public. These include local and national media coverage, publication of numerous booklets and product alerts, a web site, a telephone Hotline, a Fax-On-Demand service, the National Injury Information Clearinghouse, and the CPSC's Public Information Center. There also a variety of web-sites and other means that publicly announce recalled products. However, they are not sufficient as the figures show and there is a need for new means and technology to be invented in order to prevent those tragic events from occurring. Russ Rader, a CPSC spokesman, says recalls also depend heavily on the cooperation of the news media. In the case of the Travel-Lite, the agency issues new press releases every time a child dies in the crib. The crib is also included in the agency's "recall roundup," an annual news release that lists some of the most dangerous recalled products. Rader says that the CPSC issues hundreds of press releases every year, including video news releases for television stations. Russ Rader also said "It breaks everybody's heart when these accidents occur. They're deaths and tragedies, but they're preventable."

The companies are also trying desperately to track and identify the recalled products as can be seen by another press release issued by the manufacturer, after the death of the baby in New Jersey in August 1998. "This is a terrible tragedy we had hoped to prevent when we voluntarily recalled the Playskool Travel-Lite crib in 1993 and immediately began extensive public awareness efforts to urge consumers to stop using the products" an officer of the company said in his written statement. The manufacturer said that they have done everything possible to recall the cribs after the death of Daniel Keysar. The company has, in fact, written directly to pediatricians and to all J. C. Penney catalog customers; mailed posters to stores that carried the cribs; set up a toll-free telephone hot line; and offered consumers $60 for the return of each crib (the cribs originally sold for about $89 each). Of course, all of that was not enough and one more child, among the many who died, was strangled to death, and the tragedy repeated.

Another critical issue related to the recall system currently used is the incredible negative impact on business in general which indirectly discourage companies to put their best efforts to recall defective products. According to the United States CPSC underreporting products that could cause injury or death is a very serious problem. The main reason for the above issues is due to the means by which both the CPSC and manufacturers inform the public which is primarily based on the news media. The bad publicity through the media and videos basically saying "Sorry, we made a defective product" causes devastating financial consequences for the manufacturer of the recalled product. According to studies by Paul Rubin, former chief economist for the CPSC and professor the economics at Emory University , a company loses 7% of its revenues after each recall. It is easy to see the financial disaster to companies and to the economy of the nation in general that occurs with the current public means used to alert the user about harmful products. There is lacking of a technology that can privately and individually alert the user about a recalled and/or harmful product. The current way of recalling is also very expensive and companies have a difficult time to make more aggressive recall efforts due to lack of funds. The federal government does not want to impose too many restrictions on manufacturers because it could put hundreds if not thousands of companies out of business with the consequent uncontrolled increase in unemployment and the catastrophic effect on the economy of the nation.

Although adverse effects and reactions due to drugs and defective consumer products are responsible for hundreds of thousands of deaths and millions of unnecessary hospitalizations yearly with the subsequent incredible cost and burden on the health care system, the unintended harmful effect of a variety of products, devices, food contamination, color additives, cosmetics, chemical compounds in food, and the like also cause significant amount of harmful and even fatal events being responsible for the increasing health care costs creating a tremendous burden for the

income tax payer who is ultimately paying for not only health care but also disability that occur due to the harmful effects of some products. Most of these complications, harmful events, injury, fatal reactions and so forth could be significantly reduced with the subsequent reduction in health care costs if a cost-efficient system be implemented for identifying and locating those defective and harmful products and users with warnings and guidance provided to all of the users of the harmful products.

There is an increase in imported food and products which are more likely to cause unintended harmful effects. Public sector spending growth with adverse drug reactions is estimated to accelerate since prescription drugs grew at double-digit rates during the last few years because of increases in the number of new life-saving drugs entering the marketplace, increased consumer demand induced by drug manufacturer advertising and an increase in the number of prescriptions filled. It is expected that in the year 2000 an average of 8 to 9 drugs will be used by each American which will increase life expectancy but also will cause unintended harmful effects. Besides rising utilization (number of prescriptions) there will be also a increase in intensity (including changes in size and mix of prescriptions) which will lead to a further greater risk for reactions. It will be virtually impossible to slow the growth on national health expenditures if we cannot efficiently, privately, and timely identify, locate, prevent and provide guidance actions regarding to injury and illness that occurs due to unintended harmful effects of products. For extended care, both nursing home and home health expenditures growth are expected to grow as more disability is expected to occur due to unintended harmful effects of a variety of products. Injuries, illnesses and death due to the lack of timely identification and location of users of defective or contaminated products and drug reactions as well as food borne illnesses will boost in the coming years creating a higher demand for medical services and exponential increase in health care costs associated exponential income tax increase. It is clear then there is an urgent and vital need for technology which can privately , individually, timely, continuously, confidentially, reliably and cost-effectively track, identify, locate, inform and alert all of the users of potentially harmful products. It is also extremely desirable to have a system that returns only specific information relevant to the individual user of a unique product, and not random and/or mass information about a variety of products that do not relate to the user thus avoiding the unnecessary transfer of information and documents that are not relevant to the user.

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Even with a great recall effort combined with really massive advertising as done in the prior art is innefcient

Infants have died in unsafe cribs after those cribs have been the subject of a CPSC recall. allowing this to happen over and over and over again?" LACK OF TECHNOLOGY. With improved tracking and managing. The incomprehensible misery that preventable loss of lives brings about you must be experiencing. through such a tragic accident. Stop tragic and needless deaths. The physical and psychological effects of these injuries on both children and families are often permanent. same accident was being repeated over and over again in the homes of numbers of unsuspecting American families every year.

how many tragic repetitions

ultimate goal of a safe crib for every child.

continuing to happen at a rate of almost 40 a day, with over 50 deaths a year. If only I'd had access to information that was already known at the time! I had an urgent need to warn other parents of potential crib dangers. hope that no other families would ever have to experience our unrelievable pain.

Furthermore, there is o prior art that tracks, identifies and locates each individual user and product, nor all of the users of a particular product. DMC PROVIDES A EFFICNET RECALL SYSTEM WITH IFORMATION CONTINUOUSLY UPDATED

SUMMARY

Accordingly, it is a advantage and object of the present invention to provide a completely automatic electronic and network-based recall and information system for a variety of products including prevention and control of harmful effects of products by providing electronic data communications including an electronic hand-held portable terminal consisting of a biological and general communicator and locator, and network information system to assist the user in timely identifying a health hazard or any other hazardous situation or insults due to unintended harmful effects and adverse consequences of a variety of products as well as to prevent the occurrence of said harmful effects and to prevent the spread and continuation of said harmful effects, and in particular to track, identify and locate dangerous products and the user of said harmful products as well as alert and inform about adverse reactions and adverse effects of drugs, medical devices, food, cosmetics, and other consumer products and the like allowing the users of said products to take appropriate action in regards to a possible unintended harmful effect of said products using a system that can privately , individually, timely, continuously, confidentially, reliably and cost-effectively track, identify, locate and alert all of the users of potentially harmful products with a very-low cost electronically-based arrangement.

The apparatus and methods of the present invention consists of an electronic and internet-based recall system comprised of hardware, firmware and software that utilizes a potentially harmful product utilization database and objective variables such as objective biological variables, and/or objective factors which alter a biological variable, with said objective data as well as product use information automatically acquired, processed, and transmitted using a computer-based system integrated with a public network such as the Internet, with the purpose of timely and precisely locating an user exposed to a hazardous situation and delivering information/instructions regarding said hazardous situation or potential hazardous situation creating an automated and automatically adjusted and updated system which is reliable and cost-effective and capable of timely and precisely locating and warning said user at risk or exposed to a potential hazardous situation.

In a preferred embodiment the invention is based on a newly created and denominated product-based and product-driven system which accomplishes a task never performed before by any system and consists of a product-driven system in which reliable product information actively search for all of the individual users of a unique product and all users of products acquire information on each and every product used with said passively acquired information comprising of beneficial, detrimental, and recall information for each and every product used with the product information being delivered instantaneously as soon as said information is available, and with the product recall and warning information for all of the products utilized by each user ultimately searching and finding each user. The present invention provides a system in which each harmful product searches and finds not only each user, but also all users of said harmful product creating a system in which the harmful product finds the user, rather than the user searching and finding the product warnings and recall information needed related to the harmful products being used.

In accordance with a preferred embodiment, it is an object of the invention to provide a product-based and biological variable-based system with a location, information and recall system using preferably a packet-switched electronic transmission of data via the internet including a portable hand-held locator device carried by the user with data related to the unique product identification

primarily present for acquisition as optically encoded symbology with said data on product identification transmitted to a remote central computer server station which receives and stores the user product data and username and also receives and store information from remote recall and information sources such as government agencies, private institutions such as medical institutions, manufacturing companies, and the like. The system allows a plurality of users which have products stored in the system database to update and transmit information to the database using a public network as the internet and to receive feedback information on the products stored in the database. The central computer server station sends information and warnings, as soon as they are received, in regards to the products stored in the database to all of the users of said product via electronic communication means, preferably through the internet. The hand-held device carried by the user provides a record of all of the products being utilized by said user and biological variables with said hand-held device transmitting said data to the central computer server station using electronic means. The system uses the terms IP (internet protocol) address, domain name address, username, full internet address interchangeably to denote a specific confidential address of a user of a product. The combination of the various networks, computer units, users, server, and recall and information sources creating the location, communication and information system according to the principles of the invention is referred herein as GPI System (General Product Information System). Any variable that can be measured in a living tissue for the purpose of the description is referred herein as biological variables. Factors which alter biological variables consists of any physical or chemical action or interaction with/to a living tissue causing any change in, on, or surrounding said living tissue. Any chemical compound that alters any biological variable or any living tissue is referred herein as Drugs. Any network of computers for the purpose of the description may be referred herein as the internet.

To find 10 deadly products being sold to over 100 million users is a daunting and currently virtually impossible task, and thus 10 people will likely die due to the deadly effect of the harmful recalled product. It is, then, another object and advantage of the invention to provide a novel electronic recall system which can precisely identify all of the users of a harmful product.

It is still another object and advantage of the invention to provide a novel electronic recall system based on electronic communications via the internet.

Yet another object and advantage of the invention is to provide an electronic information and location system that can privately and confidentially locate and alert the user of a harmful product.

It is still another object and advantage of the invention is to provide an electronic and network-based information and location system that can individually locate and alert the user of a harmful product.

It is still another object and advantage of the invention is to provide an electronic and network-based information and location system that can timely locate and alert the user of a harmful product.

It is a further object and advantage of the invention to provide a system in which the database is continuously updated and items of said database are automatically transmitted over a public network.

Still another advantage and object of the invention is to provide a system in which the user of the harmful product can be located and informed about the potential hazard, but the user can remain anonymous throughout the process of tracking, location, receipt, and use of information.

A further advantage and object of the present invention is to provide a system that is continuously updated with the latest information on products utilized available to the user of said potentially harmful products.

It is yet a further advantage and object of the present invention is to provide a system that provides only proven information from reliable sources about the products utilized by the user or biological variables acquired by the user.

It is another advantage and object of the invention to provide an alert system in regards to the interaction between dynamically changing biological variables and products with the consequently timely identification of the hazard and subsequent institution of treatment or prevention measures.

Yet another advantage and object of the present invention is to provide guidelines and instructions to assist the user of a potentially harmful product before any insult, illness or injury occurs.

It is also an advantage and object of the present invention to provide an information system not only about the newly found harmful features of products, but also the newly found beneficial features of products.

It is also another advantage and object of the invention to provide the most cost-effective system for recalling harmful products.

It is also an object ad advantage of the present invention to provide an economical way for government agencies and private companies to implement their recall programs.

It is still another advantage and object of the invention to provide a report system in which the users can report any harmful event that occurred with the use of the product and/or product contamination, labeling concerns, or questionable product stability.

It is yet another object and advantage of the preset invention to provide a confidential alert system that protects against the financial disaster that invariably occurs to companies which rely on publicly announced recalls.

Another object and advantage of the present invention is to provide a system that can assist the user in identifying substances that said user should avoid without having said user to read all of the chemical ingredients described in the label of a product.

It is still another advantage and object of the invention to provide a system which informs the user of the alternative products which do not interact with drugs being used and/or the biological variables for said user and/or alternative products which may be beneficial for said user according to the information about said user.

It is still a further object and advantage of the invention to provide a system to assist government agencies in locating plants for inspection which potentially do not have good manufacturing practice.

It is yet a further object and advantage of the invention to provide a system to assist government agencies in identifying and locating imported products for collection of samples and inspection.

It is still a further object and advantage of the invention to provide the most time-efficient and orderly system by using optically encoded symbology.

It is still another advantage and object of the invention to provide a very low production cost and simple to use hand-held portable unit which can be universally and unrestrictedly utilized.

It is still another object and advantage of the invention to provide a system with information cards and smart cards with extended storage capabilities for the tracking, identification and location of a user of a potentially harmful product.

It is another object and advantage of the invention to provide a communication and information system in which the user communicates with a server and receive instantaneous information as to whether such a user is utilizing a harmful product and which level of hazard is the user exposed to by using such product.

Another object and advantage of the present invention is to provide a system in which the user seeking warning or recall information receives only information about the specific products being used, and thus avoiding being inundated with meaningless and/or random product warning information.

Another object and advantage of the present invention is to provide a system that can electronically receive not only text but also image data related to information about the harmful product used.

Another object and advantage of the present invention is to provide a system that is coupled with the most reliable and updated information sources including government agencies, manufacturers, and the like.

It is a further object and feature of the invention to provide a system for the complete delivery of health care in response to the effects of harmful products including contact and dispatching of emergency medical services, appointment schedule, laboratory testing and other diagnostic testing, prescription and delivery of drugs, and insurance approval.

Another object and advantage of the present invention is to provide a system which uses non-subjective biological, medical, treatment, and diagnostic data and variables.

It is still a further advantage and object of the invention to provide a tracking, location and identification system which allows specifically tailored information to be delivered o the user.

It is a further object and feature of the invention to provide a system in which a hand-held portable device can communicate with another hand-held portable device.

It is still another object and advantage of the present invention to provide a system that allows the timely intervention and treatment of diseases before complications occur.

It is a further object and feature of the invention to provide an interactive system for the home monitoring and self-measuring devices in the prior art described by Abreu.

It is still a further object and advantage of the invention to provide a system capable of incorporating data entry peripheral devices and coupling with various home-use data acquisition

and transmission devices as described in the prior art by Abreu as well as to provide a system that can communicate with a variety of processor means.

It is still a object and advantage of the preset invention to provide a complete paperless system for recalling harmful products.

It is still a further object and advantage of the invention to provide a system capable of using a WebTV-like configuration with a user friendly interface and locator hand-held device.

It is also a object and advantage of the preset invention to alternatively provide a system that can receive handwritten input data and voice input data, besides the preferably optically encoded data.

It is still a further object and advantage of the present invention to provide a system with acoustic coupling means which couples the hand-held device with telephone lines which establishes a direct connection with the central computer station creating a two-way telephone communication.

It is still another object and advantage of the present invention to provide a device that can be attachable to a second module such as the home measuring devices as devices described in the prior art by Abreu.

It is yet another object and advantage of the preset invention to provide a system that can alternatively communicate the hand-held locator device directly with a central computer station by telephone lines, optical means, radio frequency links and the like in order to locate, identify, and inform the user of a harmful product.

A further object and advantage of the present invention is to provide all of the above described features, advantages and benefits in which the individual user utilizes a hand-held, portable and compact locator and processor system means.

Th foregoing objects will be more fully understood by reference to the following detailed description , and other features, objects and advantages of the invention will also become more apparent and better understood from the detailed description which is described in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig1 is an overall diagram (schematic) of one preferred embodiment system of the present invention

Iecld fig – shows an electronic portable system

Preferred set of steps to acquire the unique product identifier

.....Acquire the recall info from the RIS

....To transfer info to portable

.....to central computer

tonopen schematic of – in another e,bodiment

ecld-ambulance flow chart of varoius ..

flow chart of an exemplary preferred entry porducts procedure
..... transfer of data procedure

flow chart of an exemplary sequence for implementation of a preferred embobiment=====
mostra do comeco ao fim em lock diagram

Preferred set of steps to transfer info at the point of transaction

Preferred set of steps to store information in the smartcard

Preferred set of steps to store informaiton on the iecld which occurs at the point of transaction

Fig 4 is a schematic of an illustrative memory arrangement and hardware for the main server

Fig is a diagram of the electronic information, communication, and location system according ot the principles of the invention

Fig is an illustrative diagram of a user-server model in accordance with one of the principles of the inveniton

Fig (web page) is a diagram illustrating an exemplary product recall and information lists displayed in an open window ona user's personal computer in accordance with a preferred embodimetn of the invention

Fig (other web page) is an exemplary diagram showing second, third and forth window opened on a user's personal computer

Fig (web recall info) is an exemplary diagram of a document displayed under the user,s name but remotely stored in the FDA computer

Fig is an exemplary diagram illustrating a composite document window in which the user has built a composite document based on the information in the first and second windows.

Fig is an illustrative diagram of the electronic recall documents with hyperlinks

Fig is a block diagram of the portable hand-held unit according to a preferred embodiemtn of the invention.

Fig is a flow diagram SHOWING AN EXAMPLE OF THE PROCESS INVOLVED IN THE ELECTRONIC RECALl, INFORmation and location accroding with one embodiment of the invention

DETAILED DESCRIPTION

In the embodiment depicted in Fig 1, there is shown a central main computer associated with a plurality of main frame computers and computer stations as well as a plurality of computer systems associated with portable hand-held programmable microprocessor-based units which are coupled with health monitoring devices. Referring again to the drawings, in Fig. 1 there is illustrated a preferred embodiment in accordance with the principles of the present

invention for electronic communication, information and location system for recall and information on products and biological variables including prevention and control of the unintended harmful effects of products with said system preferably comprising an electronic communication system preferably using packet-switched technology via the internet and a main server connected to a variety of entities and computation means via the internet or any public network and preferably coupled to a microprocessor-based hand-held portable unit with bar code reading capabilities.

The combination of all units with its respective functions is referred herein as the General Product Information (GPI) System. The system includes a central computer, Recall and Information Sources (RIS) computing units, Providers of Health Care (PHC) computing units, personal computer terminals which are also called computer systems, hand-held computer terminals, home-measuring devices, the internet and the user with data input and output devices such as keyboard and displays being collectively called interactive devices. The user may be human, but also can be another application which interacts with interactive devices to send information and/or receive information from the GPI system. The central server, RIS units, and PHC preferably connect to the internet using high-speed T1 or T3 connections. The user terminals hand-held or computer system connects to the internet using conventional communications interface. The computer system may consist of any workstation or any computer terminal, as well as conventional personal computers, desk-top computer, lap-top computer, hand-held computer, Personal Digital Assistant, Electronic organizers, cellular phones, television units, or virtually any computation or electronic means which are connected to the internet for the transfer of information to the user of uniquely identified products.

The hand-held portable microprocessor-based terminal unit herein referred as Individual Electronic Communicator and Locator Device (IECLD) is preferably coupled to a computer system which is connected by the internet to a firewall protected main computer. The IECLD shown in figure 1 comprises of a portable hand-held microprocessor-based unit with a keypad for selection of product categories and a wand bar code reader with said unit capable of acquiring, processing and transferring data. It is understood, though, that the IECLD can act as any of the computer system as the ones above described. The IECLD can include also keypad entry means or wireless input means for inputting or entering a unique identifier code for individual products used by uniquely identified users with said unique product codes being preferably optically encoded as for example a bar code element. Although the preferred embodiment describes the IECLD as the preferred means to acquire and enter the information, it is understood that the users of the product can enter the product data and user data directly into their computers systems for subsequent transmission to the central main computer.

For the purpose of description the portable hand-held unit is referred as IECLD and the personal computer as computer system and the central main computer as General Product Information server and the source/information entities as Recall and Information Sources (RIS) and the providers of health care entities as Providers of Health Care (PHC).

The system includes a main remote central computer herein referred as GPI server which receives, retrieves, stores, searches, processes, transfers and connects the data and/or information on products and biological variables to/from the user or/and to/from other RIS entities and PHC entities with said server being connected to the user and to various information sources and entities preferably via the internet with said GPI server establishing communications channels with the RIS and PHC computers. The GPI server is programmed to handle electronic transfer of data including conventional e-mail and has data storage and processing capabilities for storing and processing the pertinent data with said server having multiple modems and telephone lines coming into it as one of the means to transfer data, but it is understood that other physically wired, telephone lines, or wireless means, such as cable, satellite transmission, radio transmission, optical transmission, and the like as well as conventional telephone phone lines or digital telephone lines, and other electronic transmission means or any electronic transmission over the

internet or any high-speed internet connection can be used by said GPI server as communications medium. The GPI server contains the software, firmware and hardware necessary to carry out the protocols needed such as for example search applications well known in the prior art and the units comprising the system include devices which enable communications with other units such as modems and the like as well as programs needed to implement the protocols according to the principles of the invention. The GPI system includes information retrieval engines for text and multi-media files as well as capabilities to perform searches through the stored database and engines to search the world wide web and means to connect the user to web sites related to the search topic. It is understood that the invention is not limited to types of hardware and software that are used or the methods of communications that are employed since there virtually endless combinations of technology that can be employed to carry out the present invention. The GPI server is shown schematically in the drawings as one single unit, but is intended that a plurality of networked computers can be employed which allows continuation of service in the event of a hardware failure of a server as well as to provide a larger storage and processing capabilities. The GPI server operates as the central database where all the unique usernames, unique product identifier code, biological variables, name equivalent, product and user information, recall/warning information, harmful effects of products, beneficial effects of products, and product-biological variables interaction information are maintained. The stored information can be made available to the user electronically via the internet, or by conventional physically wired means, wireless or the like.

In the embodiment shown in Fig 1. the user inputs the products that are being used preferably by acquisition of optically encoded symbols with a bar code reader, and electronically transmits this information to the main GPI server, preferably through the internet, with each product being transmitted as a unique identifier for that individual product and as being utilized by a unique particular user who is identified according to a unique username. The main GPI server transfers information to/from Recall and Information sources (RIS) and to/from the users of the product with said GPI server acquiring information from RIS on products according to the product identifier, preferably the unique bar code number. The search of the RIS can be done by a human operator, but preferably uses conventional application which interacts and searches the web according to the product identifier. The user provides the unique product identifiers and biological variables by way of a communications medium such as the internet to the GPI server with data biological variable and product identifiers being stored in the GPI server under said user according to the principles of the invention. **In one exemplary embodiment, the GPI server searches the various RIS for warning or recall information according to the product identifiers which have been collected from users and are stored in the memory medium of the GPI server.** The GPI system

When the invention is implemented using the IECLD, the unique and novel bar code number for the particular product being used is acquired using the bar code reader present in the IECLD with said bar code data representing a unique product identifier and being then converted to binary element and transmitted using a communication interface to a computer system and stored as binary element for said bar code number. The product code(s) is (are) then transmitted to the main GPI server with said individual product code stored in the main server database as a code under the user's name as username and preferably a full internet address is used as means to identify said username. Every time a new product is used, the new data on the product is acquired, transmitted, and stored in the main server database under that individual user's name (username) for that individual product code.

Fig. 1 also shows the various entities and sources connected to the main GPI server via a communications network preferably as the internet, and more precisely shows the main GPI server connected to computers at government and private agencies/institutions in the US and abroad, such as the United States FDA (Food and Drug Administration), the United States CSPC (Consumer Safety Product Commission), the United States EPA (Environment Protection

Agency), the United States CDC (Centers for Disease Control), the United States Department of Agriculture (USDA), United States National Institutes of Health (NIH), United States Department of Health and Human Services (HHS), the World Health Organization (WHO), International and domestic agencies and institutions (such as for example, but not limited to the Japanese Ministry of Health and Welfare, Canadian Food Inspection Agency, German Federal Institute for Drugs and Medical Devices, French Agency for Medicine, the Pharmaceutical Inspectorate in Belgium, the "Secretariat de Salud" in Mexico, the Ministry of Health in Brazil, the US Department of Energy, the US Department of Transportation, and the like) as well as the manufacturers and distributors of the products stored in the GPI server database, medical institutions, research facilities, public computer terminals (PCT), private organizations, and the like, with said various sources and entities related to product recall and/or product information for the products stored in the memory medium of the GPI server with said plurality of entities for the purpose of description being collectively referred herein as Recall and Information Sources (RIS). These RIS computers connected to the GPI server are key in the carrying out of the invention providing a reliable source of proven information to the user. Fig 1 shows the main server GPI connected to the mainframe computers of the various RIS via particular links to a communications network such as the internet with said GPI server also connected via the internet to a personal computer of a user or to the hand-held IECLD of said user with said main GPI server receiving up to the minute updates on the products stored in the server database from the institutions and agencies described above as RIS. Although each block is labeled as a particular entity/entities or user, the present invention can be implemented by any computing device which performs the computations and communications that are carried out by said entity/entities or users. Fig 1 also shows the main GPI server connected to various providers of health care entities (PHC). It is understood that the GPI server can operate as a web server for both receiving and transmitting product identifiers and/or product information to/from the user and to/from the RIS and to/from the HCP including searching/retrieval for both text and multimedia files related to the product identifier and/or biological variable. PCT or Public Computer Terminal, mentioned above, for the purpose of the invention is a computer system located in public places in which anyone could transfer data on products being used to the main GPI server.

The system can also include home-monitoring devices herein described as health monitoring devices (HMD) interfaced with the IECLD with preferably wireless transmission of data with said home-measuring devices consisting of the ones described in the prior art by Abreu and other devices described in the prior art for home health monitoring. More specifically and for illustration and description purposes it is depicted in Fig. 1 a self-tonometer for home-measurement of eye pressure by Abreu, a non-invasive blood analysis device by Abreu, a continuous temperature monitoring device by Abreu, a conventional electronic home-measuring blood-pressure device, and a conventional electronic scale. It is understood though that any device that measure any biological variable, physical variables, chemical variables or any device, method, or system used for the delivery of health care including evaluation, diagnosis, monitoring or treatment of patients can be used in the invention and the data acquired being transmitted and stored in the main GPI server for further processing and transmission of information to the user. **It is also understood that any device which has a unique identification and interacts with patients during the provision of health care such as diagnosis, monitoring and treatment can be used in the present invention, such as infusion pumps, ventilators, EKG machines, and the like.**

Fig 1 also shows the electronic information communication system between the GPI server and the various RIS and between the GPI server and the user with said electronic information communication system presented as e-mail via the internet, hypertext markup language via the internet, or any other electronic means using a public network as well as direct point-point communication via direct log in by the user into the main server, and/or by electronic or conventional communication means between the GPI server and the user via a private

communications network. Thus the user can communicate with the main server via the internet or via direct connection for information exchange using electronic or conventional communication means. The user can communicate with the GPI server using the IECLD or a computer system. The HMD can communicate with the GPI server directly, via the internet, via the computer system or preferably via the IECLD.

The main GPI server is also connected to various health care related providers such as insurance companies, emergency medical services (EMS), medical institutions, doctor's office, laboratories, and pharmacies with said providers delivering any of the aspects of health care according to the instructions received from the various RIS and GPI server in regards to a potentially harmful product. Thus, if a harmful product is known to cause a life-threatening situation which requires emergency treatment the EMS is contacted and a team dispatched to the residence of the particular user of said harmful product, if a harmful product is known to cause a medical condition that requires medical attention then a doctor's office or medical institution is contacted and arrangement for an appointment and transportation made for that particular user of said harmful product, if a harmful product is known to cause a medical condition that requires laboratory or further testing then the tests to be done and facilities where said tests should be done are identified and the information sent to the particular patient at risk by using said harmful product, if the harmful product is known to require treatment with a medication or antidote, then the necessary prescription is issued by the doctor's office and appropriate pharmacy contacted for delivery of the medications needed by the user of said harmful product.

Fig 1.also shows the connection among the main server and the various RIS, and if information on a uniquely identified harmful or recalled product is received/acquired by the GPI server from a source such as the FDA, CPSC or USDA, then the GPI server searches and retrieves all of the users of the harmful or recalled products and preferably electronically send by e-mail said information to all of the users of said products with the interactions and communications involving the GPI server, RIS and users being preferably automatically carried out by appropriately programmed computation and processor means. This information would also be available to the general public for easy access by logging into the GPI site or by web based e-mail message for the registered users.

It is also illustrated in Fig. 1an autodialing or paging system which is activated if the users of a product is identified as using a product that requires immediate attention as an urgent situation, but still do not require emergency equipment with said decisions on what service is needed based upon the response necessary to treat and/or prevent the unintended harmful effect of a product as recommended by the RIS. A variety of other means to alert the user about an urgent message such as paging, audio and/or light signal in the computer system or IECLD, and the like can be used besides autodialing.

There are also connected to the main GPI server for the purpose of illustration a plurality of users who can be located in virtually any part of the world and here are referred as domestic users, international users, as well as a GPI web supported site in which anyone can enter and send to the main GPI server via the internet the harmful effects encountered with products, thus creating an additional collection system for identification of potentially harmful products with said information on harmful effects being sent to the various RIS by the GPI server.

The main GPI server, besides receiving information from the various RIS, also has applications to search for information on the products which are stored in the various RIS as well as applications to search for the products and usernames stored in the GPI database. If a product is found to be harmful or is recalled with said information being transmitted or acquired by the main GPI server, then said GPI server identifies and retrieves all of the users of said harmful product according to the brand name of the product or preferably according to the product unique code identification number and if there is any matching between the username and the brand name or product unique code number, then the server will retrieve the usernames or code numbers of all of said users of said harmful product and attaches the information about the

hazards and instructions related to said harmful product to a warning message The GPI server then will electronically transmit to all of the users of said harmful product the alert and information about the product preferably with an attachment with the detailed information utilizing conventional bulk e-mail software or via other electronic and conventional communication means. Alternatively, the main server transmits the information to the user's web-based e-mail address with said web-based e-mail being supported by a GPI server. The GPI e-mail server contains all of the usernames related to the product identifiers with said usernames and products names stored in the GPI database. **Fig 1A shows a simplified flow diagram illustrating the use of the recall system for newly acquired products and interaction with biological variables. In accordance, the user acquires unique product identifiers with the bar code reader wand and the biological variables with the HMD at step--. The user then sends to the GPI server the data acquired using communication medium as the internet at step--. The system then searches the database for a match to the product identifiers and biological variables interaction at step---, and then at step--- in response to the commands received the system send the information/documents related to the product identifiers and biological variable interactions to the user. It is important to note that the information transmitted to the user may include textual and/or multimedia documents stored on the system, the GPI server but also said information/documents can be accessed via the network and stored at one or more remotely located computers. The computer programs are comprised of instructions which when read and executed by the computer system and/or GPI server makes said computer system and/or GPI server to perform the steps necessary to carry out the invention according to the principles described herein this specification.**

Each time that a user send information to the main GPI server, as part of the application and registration process, said user is automatically registered with the GPI server web-based e-mail. Any product information or values of biological variables that are send by any user automatically register said user with the GPI web-based e-mail of the main GPI server and allows said user to have immediate and confidential access to the information on the potentially harmful or beneficial effects of the unique products being used. Any time information on a harmful product is sent to the central GPI computer server station from the various RIS said information is checked against the server database and if any user is identified as utilizing the harmful product, the warning message and instructions about said harmful product are sent to the users via conventional electronic mail, or via GPI server web-based e-mail, or via a web site supported by the central GPI computer server when the user logs on that web site and proper identification is established, or by autodialing or paging or conventional communication means in case of critical life-threatening situations and inability to connect via the internet. The GPI server also uses conventional keyword, natural language, fuzzy logic, text engines, and other conventional searching tools to find information requested by an user transmitting data to the GPI server about a particular product/biological variable as well as to find the information on GPI stored products which may be located in the various RIS databases described such as FDA, CPSC, EPA, manufacturers, and the like. Whenever the GPI server is configured as a web server, conventional web browsers can be used to transmit product identifiers and biological variables. The system of the invention preferably uses hypermedia and graphic medium system as information provided via the World Wide Web with the user of the invention being able to access updated recall information on the drugs and products being utilized by said user from around the world from any computer terminal with direct communication with the GPI server or via the internet by logging on the GPI web site or by retrieving his/her e-mail in a conventional manner, or any other means to retrieve electronic data as well as verbal messaging and e-mail with a text-to-speech electronic voice synthesizer. Thus the GPI server can be accessed in a variety of ways by the user including via a web site in the internet, internet service providers, on-line networks, direct link, and the like.

The information from/to the user to/from the main server (GPI) as well as from/to the

main server (GPI) to/from the RIS preferably uses transport-level protocols and datagram connection such as TCP/IP protocol suite preferably using a packet-switched network, although is understood that a circuit switched or other network connections can be used. It is also understood that other network communication protocols such as Virtual Reality Transport Protocol (VRTP), Secure Hypertext Transport Protocol (SHTTP) as well as other emerging protocol technologies can be used in the present invention.

Any medical information of an individual is an extremely sensitive and confidential matter, and although encryption means and other applications to protect against attackers can be used when transmitting said medical data of a user there are no ways to provide full protection and confidentiality. One of the features of the invention consists of the provision of a system that keeps the name of the user of the medications and products confidential at all times by using an ID as can be conventionally done in transmission over the internet, for instance Mr. XYZ is used instead of Mr. Jones. In accordance, the medication "X" is not associated with Mr. Gerald M. M. Jones who lives at 111 Main Street, but with Mr.XYZ@GPI.org, and thus Mr. Jones identity as the user of the drug is basically further protected. The system of the present invention uses the conventional Domain Name System which allows the user of the potentially harmful product to remain anonymous and thus the sensitive matter of what type of drugs or products said user is utilizing is kept confidential with information about the hazard associated with a certain drug being sent to the user's internet address under the user's internet name and address, assuring thus the required security and confidentiality that is needed through the whole process of using the product, retrieving information about the user of the product, retrieving information on the recalled products and sending the information to the user about the recalled products. The information on the recalled product is converted to the appropriate internet communications protocol for transmission to the user of said harmful product. Each user of any product which is stored in the GPI database has a specific address such as the Internet Protocol (IP) address and has a user name combined with the IP address as it is conventionally done creating a full internet address. For example, Mr. Gerald M. M. Jones is the user of drug "X2" and his username is Mr.XYZ and his full internet address is Mr.XYZ@GPI.org. The GPI part of the domain name in the present invention is preferably the GPI server attached to the internet which receives the information on drugs being used, but it is understood that any IP address as a four-part number or any domain name or code can be used in the invention, as long as uniquely and preferably confidentially identifies the user of the various products and drugs. The full internet address is stored in the GPI database as it is or preferably under a code associated with said full internet address. All of the codes and names of the products used are acquired according to the principles of the invention, then transmitted and stored under said username's code, meaning the user's full internet address. It is intended that the user identification in the database is preferably the username with the IP address or a domain name. It is also intended for the purpose of the description herein that the terminology IP address or domain name or full internet address means the username combined to the IP address or the username combined to the domain name or any other means which uniquely identifies the user of a product.

The GPI server is continuously updated on drug "X" by government agencies such as the FDA, the manufacturer of the drug, medical practitioners prescribing the drug, patients using the drug, and the like, such as for example receiving information related to marketing surveillance by the FDA on drug "X". Whenever, there is a recall or relevant information by the FDA concerning drug "X", this information is actively or passively transferred to the GPI server which then search and identify all of the anonymous users of drug "X" which are stored in the database, with the GPI server subsequently electronically sending the information and instructions on how to proceed in regards to the use of drug "X" to the user Mr.XYZ@GPI.org, and to all of the other users of drug "X", without even the central GPI server or any third party knowing the true identity of the user, and thus reliably and privately identifying, locating, and instructing all the users of drug "X" or drug "X2" if lot X2 is the one being recalled.

The system can operate in a variety of models and Fig 2. shows an exemplary diagram of the user computing units and a home-monitoring device. The computer system includes a display device, a display screen, a housing which encloses standard computer components, interactive devices such as keyboard, and microphone, as well as a mouse and built-in or external modem. The IECLD preferably includes a touch screen, built-in barcode reader, a keypad, a housing which encloses standard computer components, external antenna, optical transceiver, and a modem. The home monitoring devices includes components and structure described by Abreu in US patent 5,830,139 and pending applications and will not be described herein. Figure 2 also illustratively shows the flow of data and information to and from said computing units with such flow of data preferably controlled by the central GPI server and routed over the internet.

The GPI System keeps track of all of the recall information provided and/or retrieved from the various RIS and then locates the unique user of the unique product. The main GPI server uses standard applications to search for recalled products and/or receives information about recalled products from the various RIS. If a recalled product or a harmful effect or beneficial effect is found, the GPI server retrieves and stores the name or preferably the code number for said harmful product in its database, and then searches for usernames which are using said harmful product and matches the code sent by the RIS with the code of products used under the username. If there are harmful products codes under said usernames, then said usernames are retrieved, and then the level of severity or risk of the warning message is evaluated. If codes 1 to 3 are found in the warning information received (1= minimal, 2=moderate, and 3=high), and username has an active internet address then conventional bulk e-mail software is used to electronically send the warning message/web pages on the harmful product to all the usernames associated with the code for said harmful product. If code 4 is found (4= critical with life-threatening risk or fatal reaction) in the warning information received then e-mail with warning message/web pages on the harmful product is sent and an autodialing or paging terminal dials all of the users of the potentially lethal product and informs by conventional message means about the potential fatal reactions or problems with said harmful product and advises the user to check the GPI web site and its GPI e-mail, and if emergency care is required then the EMS is contacted and dispatched. It is understood that depending on the level of severity a variety of audible and/or visible signals can be used which corresponds to said levels of severity with said signals displayed on the screen of the computer systems or IECLD. When the RIS sends a warning e-mail or other warning information via the internet to the GPI server about a recalled product or harmful product code number, then said GPI server computer sends a request to check its database for the username and IP address which are associated with said harmful product code number, and when said username and IP address associated with said harmful product is received back, then the GPI server matches said usernames and IP addresses with the warning message and/ or web pages to all of said usernames and IP addresses which in the GPI database are associated with the harmful product code number, according to the level of severity as previously described. Alternatively, if only the names of the products are used in the case of a comprehensive recall or when no such codes are available, then the GPI server uses the name of the product and not the code to identify, locate and warn the users of the product in the same manner as described above.

The information about products (codes and/or names) being used and stored in the GPI server database can only be accessed by the user of said products who enter the proper name and password. To further assure the confidentiality of the information about products being used, biometric identification devices such as iris scanners, retinal scanners, fingerprint reader, voice recognition systems, and the like can be used as means to verify identity of the user before accessing the GPI server database or using the IECLD. The GPI server continuously receives or/and acquires update on the products with the new information about the harmful products immediately transmitted to the unique user of said harmful products. A menu-type message can be generated with the most critical hazard placed first with a decreasing order of severity

presented when the message/warning is transmitted using conventional e-mail. In another application, certain information for example the effects on the heart by any of the products stored can be of interest to a certain user and thus said user has the option to store and index said particular information in the GPI database under said username to enable the user to later review products which were used that could have affected the heart, and this information can be transferred to the user's doctor.

The GPI server also checks the presence and/or values of the biological variables of said user looking for abnormal values and non-compliance with timely monitoring biological variables. If the user has for instance not sent or it is not recorded blood sugar in the last week for said user who is diabetic, then the GPI server will e-mail a note to said user to inform and encourage the user to monitor his/her blood sugar on amore frequent basis.

The acquisition and transmission of signals corresponding to biological data or factors which alter said biological data utilize the hand-held portable device herein referred as Individual Electronic Communicator and Locator Device (IECLD) with electronic data being communicated over a public network such as the Internet to the central GPI server which will provide feedback information according to the biological and/or product data electronically received. The electronic feedback data is automatically transmitted back to the user's computer or/and the user's IECLD, however is understood that any computer terminal connected to the internet can be used by said user in receiving the information according to the principle of the invention.

DESCRIPTION OF IECLD-- It is understood that the IECLD is preferably a hand held device for the input of data, but other forms of imputing data such as using a personal computer keyboard and the like can be used in the present invention. Alternatively, data input into the portable IECLD can also be done using RF or optical input or an onscreen keyboard with said data entered by a medical practitioner, health care professionals, clerks, or the users themselves.

Referring to Fig. 3, there is shown a drawing of an illustrative hardware arrangement of the portable Individual Electronic Communicator and Locator Device (IECLD) comprising a hand-held device which can be carried by the user and utilized by a particular individual to acquire, process, transmit and receive information on products being used by said particular individual and biological variables with said ECLD consisting of a housing which contains a conventional programmed microprocessor with data processing and storage units which controls the operation of the device, communication interface and communication ports, built-in bar code reader apparatus, warning lights, optical transceiver exposed through the housing preferably working in the infra-red wave length, a numerical keypad, and a modified keypad for the five main products that are recalled which enables manual selection of the type of product being scanned with the five main products consisting of drugs, medical devices, toys and baby products, cosmetics, food, and miscellaneous. The IR interface receive/transmit signals such as biological data acquired from home monitoring systems as well couples with other interface to transmit signals such as biological variables or/and product identifiers to a computing system with said computing system being connected to a public network as the internet. The hand-held terminal is preferably provided with a variety of software applications and decoding elements for optically encoded symbology with a system configuration including a scanner module for bar code reading. Alternatively, the hand-held terminal IECLD is provided with voice input and/or voice synthetizer modules and/or means for handwritten input data and/or typed input data and/or manual data entry with an electronic keypad. It is understood that any type of product group such as for example household items could be used, but those are less likely to cause substantial and frequent harm and increased health care cost as with the above main five categories preferably used (drugs, cosmetics, food, baby/toy products, medical devices,), and such other group products are included under miscellaneous. It is intended that any variations or group products could be selected with keypads addressing other group products. The device can for instance be

programmed to address particular group of products such as, but not limited to, automotives, appliances, furniture, lighting products, outdoor products, clothing, electronic devices, electrical devices, environmental products such air conditioners, household products, sports/exercise, and so forth. Fig 3B shows an illustrative diagram of the IECLD comprising of communication ports, a power source, a conventional modem which can be connected to a main server via electronic or conventional communication means, a RF transceiver/modem coupled to an antenna for wireless transfer of data, non-volatile RAM memory, I/O ports, optical transceiver, optical sensors/bar code readers and decoding devices, visual and audible indicators, microphone, and a display with the output of the microprocessor being supplied to said display through conventional LCD driver circuit which conventionally decodes and multiplexes the data to be applied to the display. The well known parts of a computer arrangement such as random access memory (RAM), read-only memory (ROM), and so forth for convenience, are not shown.

The bar code reader apparatus preferably used in the invention, due to its low-cost and low-power requirements, consists of a LED bar code reader with low-light levels and of the direct contact type. However, it is understood that non-contact type bar code readers such as laser-based can be used in the invention, but are more expensive and consume more power. Virtually any bar code reading technology can be used in the present invention including, but not limited to, imaging technology, CCDs, and the like. The system also allows for direct wired and wireless communication and duplex transmission with a computer central station. The input of product identification is preferably accomplished using the bar code reader, however, manual entry using the keypad or RF wireless input of product identification or any conventional wired or wireless input of product identification can also be used. The IECLD also have conventional encoding and decoding programs which allows the **IECLD** user to read messages as well as to view multimedia files related to product used by the user with said information transferred from the GPI server.

In an exemplary embodiment data such as drugs used by a patient are entered by scanning a newly created bar code element preferably separated from, the conventional UPC code. The new product identifier of the present invention encodes information of the name and characteristic of the drug, date of manufacturing, plant location, serial number, and its lot number which is called BarCodeData (BCD) or unique product identifier (UPI). BCD or UPI is a unique identifier of the product and the characteristics of the product such as concentration and strength, serial number, plant number, date of manufacturing, and lot number. The UPI can be also alternatively optically encoded in a PDF417 format which due to the high information density and capacity can include all of the information regarding the individual product such as test summaries, components and parts used, personnel involved in the manufacturing, manufacturing process, and so forth. Thus, the UPI which is optically encoded gives all of the information necessary for the recall of any particular individual and single product. It is important to note that the conventional UPC codes consists of an Universal Product Code which is universal and does not encode detailed characteristics of the product as needed for recall of individual and single product or a certain number of units of the product with same UPC code, and thus the currently used UPC does not allow a single and individual recalled product to be located. If for instance there was a recall of 5000 units of a lot of a tampered over-the-counter drug, and the conventional UPC code was used to identify the users according to the principles of the present invention, and let's also suppose that the company has sold 5 million units of the recalled drug. If then the GPI system were to use the conventional UPC code to identify the users, all of the 5 million users would be identified instead of only the 5,000 users who actually bought the product from the tampered lot. As one see the system could be implemented using conventional UPC, but it is far from preferred due to the possible excessive number of units being recalled. On the other hand, if the current invention was carried out using the UPI only the 5,000 users at risk would be located and warned, thus creating an incredibly cost-effective recall system for the users, the companies, and the government. The BCD or UPI could be used separately but also possibly in combination with the conventional UPC code. For instance the addition and/or substitution of few encoded

symbology or numbers to the UPC could provide the needed unique identifier data as described above, and thus be easily implemented and will consist of a modified UPC, now called UPI. This modified UPC is very easy to implement and thus the preferred embodiment. It is important to note that U of UPI stands for Unique completely contrary to U of UPC which stands for Universal, with the UPI meaning a completely novel means to identify a product with optically encoded symbology.

The computer system of the user and/or the GPI server contains the name equivalent data that can be used to generate the name of the products scanned according to their UPI. For the purpose of the description the UPI can be a modified UPC, a separate bar code, a two-dimensional bar code with or without the UPC, or any other machine readable format that uniquely identify a product according to the principles of the invention. There are some situations in which the conventional UPC could be used as some of the following examples will illustrate. If the total number of units sold is similar to the number of units tampered, for instance according to the above example, if 5,000 units are recalled, but the total number of units sold is less than 6,000; or if the recalled units poses immediate and 100% fatal threat, then a comprehensive recall using UPC code could be used. As can be seen, although, UPC can be used in the system of the invention, the most preferred way consists of using the BCD or UPI (Unique Product Identifier). The bar code element UPI is a unique identifier of for example drug "X". The bar code data is the converted to binary element and transmitted using a communication interface to a computer unit and stored as binary element bar code number 0001000110 for drug "X" as an example. The drug "X" is stored in the memory of the computer system with said data as drug "X" being automatically electronically transmitted over the internet to a central computer server station, the GPI server. If for instance the user Mr. Gerald M. M. Jones starting using drug "X" that came from a different lot, for example, one that included a new coating with a new color additive used, then a new unique bar code element for that product is used, and the new data is stored as for instance "X1" with UPI 0001000111. If Mr. Gerald M. M. Jones starts using drug "X" which comes with a tablet of larger size, then a new unique bar code element is used to identify the product and is stored as for instance "X2" (UPI 0001000112), and then "X3" (UPI 0001000113) for a formula manufactured abroad, and so on. Data entry using optically encoded symbology provides a virtually error-free entry system and a time-efficient and cost-efficient mode contrary to written and/or manually entered or typed data. The large amount of data on the characteristics of medication "X" is conveniently and automatically acquired as a bar code number, and then processed, and transmitted over a public network such as the internet to the main GPI server.

The bar code reader acquires the information on the characteristics of the product which are necessary for precise identification in case of a recall. The identification data on the products is then preferably later transmitted to the user's computer system via IR means, RF means or via conventional physically wired downloading means to a computer terminal with the processor executing the programs in the memory necessary to carry out the function. The IECLD include memory means which store the data on the product and communications port for downloading the data at the user's computer system with said user's computer system having capabilities to connect with a public network such as the internet. Alternatively, the IECLD includes computer terminal means having capabilities to directly connecting with a public network as the internet, and thus bypassing the user's computer system (personal computer or desktop computer). The IECLD also provides for duplex communication to and from the GPI central computer station using conventional direct communication via telephone lines or wireless via RF means.

The bar code data related to the precise identification of the product acquired by the portable hand-held device is uploaded to the GPI server for storage via conventional or electronic communication means with processing and transmission of data being performed by the microprocessor using conventional software. The data generated by the microprocessor can also alternatively be supplied with typical wireless transmission to the user's computer system.

The portable hand-held IECLD provides means for entry, storage, processing and transmission of the unique characteristics of a product to a central GPI server with said central GPI server checking its database in order to update and/or generate files according to the data transmitted by the portable hand-held IECLD. According to the principles of the invention, if there is any information stored which corresponds to the product identifiers transferred, said information is retrieved and attached to a warning message which is then transferred back to the individual user of product as previously described. Since the IECLD is portable, hand-held and compact said IECLD can be easily carried to different places and during trips and have thus applications in virtually any environment including, but not limited to, doctor's office, hospitals, pharmacies, grocery-stores, department stores, hotels, and the like, allowing easy acquisition of information on products being used as well as easy retrieval of information by direct connection of the IECLD with the internet for directly accessing the GPI server for the information about recall in regards to the products being utilized by the user. Fig 3C shows a frontal view of the housing with a modified keypad for selection of product groups before products are entered. Fig 3D shows the **IECLD placed within a receptacle in the housing of the home-monitoring devices by Abreu with said IECLD being a detachable unit.**

The apparatus and methods of present invention allows acquisition, storage, transmission, and processing of :objective biological function, objective biological variables, and objective factors that can alter said biological variables such as the use of a variety of medications. The system of the invention provides a display of the information needed by the previously located user in how to manage the hazardous situation as well as an automatic update of information and guidance according to chronological changes of the biological variables that would be otherwise undetected, thereby permitting the user to take timely appropriate action and having control over said hazardous situation. The system of the invention provides not only display and guidance/instructions on current hazardous situations, but also may predict the potential for a hazardous situation to occur before it takes place by continuously analyzing the data that is transmitted for the purpose of intermittently providing information and alerting the user about potential imminent hazardous situations before said situations actually occur. *The systems sets the criteria according to the data received from the user and the criteria is continuously adjusted in a graded manner in accordance with the updated data that is transmitted by the user and RIS.* If the criteria is met the user automatically receives a warning/information about potential hazardous situation and/or guidance/instruction without the interference of subjective considerations nor the need for a human observer to select the information. The system of the invention also provides and display information to the user about transmitted biological variables or factors that alter said biological variables with the purpose of improving understanding and comprehension regarding said biological variables or factors which may alter biological variables such as interactions with drugs and other products.

In reference to figure 4, it is shown an illustrative block diagram of the GPI server including CPU and an exemplary memory medium with an illustrative memory arrangement containing databases including product database, biological variables database, interaction database, a RIS alert database, a personal information database with an acquired personal database, and the user database and as well as conventional modules, database management modules, search modules encryption/decryption modules, time/date modules, transmission modules, e-mail modules along with secure server-based electronic mail application, clock, operating systems, RAM, ROM and other typical server applications and hardware well known in the prior art. Although the GPI system preferably uses searching with ASCII character and numerical matching and comparison, it is understood that graphics, multimedia, sound, and the like can be used according to the style of database and computer applications utilized.

Still in reference to figure 4, the CPU interfaces with the operating system and may consists of a single or multiple high-speed processors operating in parallel or in series executing applications stored in the memory devices, RAM, and ROM to carry out the necessary functions

illustrated below. The CPU receives UPIs and biological variables from the user and information on UPIs from the RIS preferably via the internet through communications interface, and stores the data from the user in the product database, user database, biological variables database, personal information database, and stores the information from the RIS on UPIs and/or biological variables in the Alert database and on interactions in the Interaction database according to a **criteria set forth below.**

The Product database includes Drug database in memory area# , Cosmetics database in memory area#, Baby/toy products in memory area#, Food products in memory area #, Medical device products in memory area#, and MIscellaneous in memory area#. The product database includes the usernames associated with the code number or name that uniquely identify each product being stored in the database, preferably the bar code numbers as the UPI according to a preferred embodiment of the invention. The product database maintains a list of all products stored according to the product category and contains individual product records with all of the users of said individual product according to the product category. Thus each UPI may be associated with a plurality of users. More specifically, the product database maintains data on products according to the categories including the Drug database which contains the UPI for the drugs transferred by the user and all corresponding usernames using said drug. The Cosmetic database contains the UPI for all cosmetics and associated users of each individual cosmetic UPI. To further illustrate, the Food database contains the UPI for food products and corresponding usernames, eg, IP addresses associated with each food product, the Medical devices database contains the UPI for the medical devices with corresponding usernames, eg, IP addresses, the Baby/toy database contains the UPI for the infant products and toys with corresponding usernames, eg, IP addresses, and the Miscellaneous database which contains the UPI for miscellaneous products according to the invention and corresponding usernames such as the IP addresses. The product database also maintains for each UPI a plurality of document records, textual or multimedia which are representative of the UPI stored. For example the UPI for a certain drug has associated document records concerning the indications, known side-effects, known drug interactions, description, chemical formula, and the like stored in the database for said drug UPI.

The user database includes the name of the user and associated UPIs for said user and maintains a list of all usernames stored with all of the UPIs associated with each individual user. The biological variables database includes the values acquired by the various HMD and are located in memory area# and the standard normal values for biological variables in area# which allows transmitted values by the user to be correlated to normal standard values, and memory area# has the pathological diagnosis associated with abnormal biological variables and is called association area. This association area# contains the diagnosis associated with the abnormal biological variable, for instance, increased eye pressure indicating glaucoma, elevated blood sugar indicating diabetes, and son on. The product interaction database has updatable fields including the most commonly known interaction between products and biological variables. The data on interaction of drugs with biological variables and other products in memory area#, interaction with food in memory area#, interaction with cosmetics in area#, and interaction with medical devices in memory area#. If for example user acquire eye pressure (biological variable) at home with HMD as described by Abreu, and said eye pressure levels are transmitted to the central GPI server, then, the CPU in the GPI server receives the biological variables (eye pressure) and store said value in the biological variables database area# which is then evaluated against the normal values area#, and since the values for example are high which means glaucoma, then the CPU searches the product database with the criteria "glaucoma", in order to identify products used which meet the search criteria. If any record representative of any UPI is associated with the criteria glaucoma, a match is found and the information transmitted back to the users associated with said UPI. In a more descriptive form, if the eye pressure is above normal limits, let's say as an illustration that pressure in the right eye is 28 which puts the patient

at risk of glaucoma and blindness. Then, the system naturally informs the user about the risk of blindness due to glaucoma, but most important the system then matches that information "increased eye pressure or glaucoma" against the various products (UPI) stored by the user at risk of glaucoma and check to see if any of the products in his/her database is contra-indicated for someone with glaucoma. If for instance said user has stored under COSMETICS a code for a steroid based-shampoo, then the system identifies the match steroid with "contra-indication glaucoma" as harmful and automatically send the appropriate alert to the user according to the principles of the invention. If for instance an user buy a moisturizer skin lotion (UPI # 111211314) and if later on, for instance the FDA send a warning about a moisturizer skin lotion (UPI # 111211314) which contains unlabeled amounts of steroids, said data "steroids" is checked against the biological variables database which contains the usernames associated with the disease, in this case increased eye pressure data which is labeled as glaucoma. The system then identifies the match "steroid lotion-glaucoma" as harmful and automatically alert all the users of UPI # 111211314 and with increased eye pressure that they are at high risk of blindness by using the skin lotion. Since the information was received from the FDA and there is risk of injury/illness, all of the users of said UPI will be informed about the newly found information on steroids present in the skin lotion allowing all of the buyers of said skin lotion to know the risks related to continuing using said skin lotion. The user with increase eye pressure is informed about the dangerous situation although said user was not even aware that steroid could lead to blindness in an user with abnormal eye pressure. The invention thus gives the information to the user even without the user knowing the meaning of the ingredients or warnings on the label. Furthermore, even if the user knew that steroid could lead to blindness in someone with glaucoma, without the invention the user would have to search through thousands of daily warnings and then by chance identify the skin lotion he bought it as containing unlabeled amounts of steroids. Another example will further clarify and demonstrate the urgent need for the invention. If the user for instance is prescribed a common drug for high blood pressure such as verapamil (a calcium channel blocker), then such drug is stored under said user name. Let's suppose the same user then buys and store under his name grapefruit juice. As soon as the identifier grapefruit is entered the system identifies the harmful match verpamil-grapefruit juice and alert the user about the dangerous interaction. "A bioflavinoid present in grapefruit juice interacts and inhibits the P-450 enzymatic pathway in the liver. The decreased first-pass P-450 metabolism increase the concentration of verapamil with the consequent significant increased pharmacological effect of the drug. The increased effect of verapamil caused by grapefruit juice can lead to severe hypotension and even fatal event depend on the dose and patient susceptibility, besides car accidents that occur due to impaired reflexes or fainting on the wheel. As soon as the harmful interaction is identified, a warning message is sent inform the user to avoid grapefruit juice. If the user had transferred information on orange juice, the system would not identify as harmful interaction with verapamil and no warning would be sent. The invention thus optimize electronic transmission creating a cost- and time-efficient system which only relevant information is sent to the user. The user does not need to know what is the meaning of the abnormal biological variable and the interaction with products stored. Furthermore, the user does not need to know that a product being used can fatally or harmfully interact with another product being used. The system of the invention provides all of this life-saving information automatically regardless of the knowledge of the user in regards to the products being used. If the user, then, purchases and transfer information on a certain product, even if said user does not know the ingredients of said product the system of the invention will alert the user about potential interactions between said products with products stored in the product database and/or between said product and biological variables stored in the biological variables database. Any interactions newly received from RIS are stored in the known interaction database according to product category.

Fig. 4 also shows the Alert database which includes data on harmful effects of products and harmful interactions stored in memory area#, data on beneficial effects of products and

beneficial interactions stored in memory area#, and recall data stored in memory area#. Whenever any of the RIS transfer products alert, the CPU of the GPI server receives the UPI information and store said UPI information in the Alert database according to the type of effect (B=beneficial, H=harmful, or R=recall). The Alert database tracks and includes all of the data warning, product information and recall information on products (UPI) received/acquired from the various RIS ranked according to the level of importance/severity 1 to 4 and according to the type of event (B, H or R) with said data on products (UPI) being checked against the product database. If the search process identifies codes (UPI) or names stored in the products database that matches the code (UPI) or name of the products received from the RIS, then the usernames and/or IP address which stores the product codes (UPI) are identified with the subsequent electronic transfer of the information/message on the products to said IP address. The CPU which is preferably programmed to automatically search the product database uses the UPI number as the search criteria and then searches the product database to identify the same UPI number and the users associated with said UPI number. The users are then identified and the warning information on said UPI transmitted back to all of the users of the product (UPI). The data on products transferred from the RIS is also checked against the biological variables database and interaction database of the users. If the search process identifies biological variables that matches the UPI information transmitted, then the usernames with IP address or domain name which stores the biological variables are identified with the subsequent electronic transfer of the information/message to said IP address or domain name. For instance if user Mr.ABC@IBM.com has transferred liver enzyme values using the Abreu HMD which were elevated and consistent with liver disease, then the biological variables database for said user indicates "liver disease". When the RIS transfer information about drug Rezulin associated with "contra-indication liver disease", then the CPU stores the data in the harmful Alert database, and then search the biological variables database and in this case finds a match for the criteria and then send a warning to Mr.ABC@IBM.com about drug Rezulin being contra indicated to patients with liver disease. In this case the user Mr.ABC was not using the drug Rezulin, and further search did not identify the UPI for Rezulin associated with his username. In this manner the GPI system acts in a preventive manner by informing the user on what to avoid, and thus helping to preserve the user's health and simultaneously saving money for the user who did not waste his money buying an expensive drug which ultimately could harm said user. Every UPI and particular information which arrives from the RIS is used as a search criteria. The CPU is programmed to search the product database, the biological variables database, interactions database, and the user database according to the principles of the invention and then transmit back the information associated with the UPI and/or biological variable back to the user.

The personal information database includes fields such as all the data submitted by the user to the GPI server during the registration process including a unique IP address with a username and/or code and/or password. The user may send his/her name, but is preferred that the user remains anonymous and for example just use an e-mail address with a pseudonym. Each new registered user can also be assigned a unique user identification number. The invention can be carried out only with the electronic e-mail address, however optimal use of the features of the invention may require some additional information such as age, biometric elements, demographic information, medical information, personal information, family history, insurance information, primary care doctor, preferred and/or nearest pharmacy, preferred laboratory, and the like with some of the areas potentially being a pointer to medical and insurance data stored at the user's medical institution and insurance company. If the user includes allergies in his personal acquired medical database to a certain product, the product name and/or other identifier are then used during searching. If the patient is allergic to peanuts for example but does not have UPI with a product with an undisclosed peanuts, then any time a new UPI is sent by said user to the GPI server, then that transferred UPI is checked against the identifier stored in the allergy field (peanuts), and if there is a match, (peanut protein present) then a warning is sent to the user who

transferred the UPI. If the user on the other hand has already stored in the product database a certain UPI for example 1212131, and then if the GPI server receives information from the RIS that a certain product UPI 1212131 was found to have undisclosed amounts of peanuts, then the search criteria "UPI 1212131 peanuts" is checked against the allergy field which identifies the user as allergic to peanuts. The CPU searches the product database and find in the Food memory area a match for the criteria, this indicates that the user is both allergic to contents of the UPI transmitted by the RIS and also has stored information indicating that the user is potentially consuming food contaminated with peanuts. The CPU then transmit the information back to all users of the UPI 1212131 as warning for product containing undisclosed amounts of peanuts using regular electronic information conventionally done for the non-peanuts allergic users. However, for the users identified as allergic to peanuts and also using the UPI which contains peanuts, then an urgent alert is transmitted by autodialing, paging, etc, besides the electronic messages, since consumption of peanuts by said alergic user can lead to a fatal event. In another example, the user Mrs.LK20@hotmail.com transfer a UPI 0911232425 related to a Baby-toy product to the GPI server, in this case the UPI for a certain portable crib "Travel-Lite". The CPU of the GPI server is programmed to receive and store said UPI 0911232425 with the respective username Mrs.LK20@hotmail.com in the Baby-Toy database, with the CPU then searching the Alert database for any information related to said UPI. In this example, at this time of searching, there was no match for said UPI in the Alert database. Few months later recall information for UPI 0911232425 is transferred from the CPSC to the GPI server, and accordingly stored by the CPU in the Alert database recall area#. Any UPI stored in the Alert database is automatically compared against UPI stored in the Product Database, and if there is a match the information associated with the UPI is transmitted back to the user. In this example, Mrs.LK, although, completely not aware of using a deadly crib, receives the information immediately as the CPSC finds that the crib is unsafe or may have killed a child as usually occur with the product first causing injury and then being recalled. Besides Mrs.LK20@hotmail.com all of the other users of the deadly crib are informed about the fatal danger posed by the product. The Travel-Light company can then reach all of the users in the most inexpensive way, besides not suffering the financial disaster that occurs with the publicly announced recalls since the company virtually is obligated to continue advertising the "wrong-doing" until every recalled crib is identified. The Travel-Lite company saves surely quite a lot with the present invention: saves money by not spending with broad regular advertising, saves by not having to pay product liability settlements, saves by not having to pay health care and/or disability costs related to the use of the harmful product, avoids loosing money or going out of business by not having to basically say to the public in the public media over and over "our company kills children" until the last unit is recalled, but most important of all by using the present invention, the Travel-Lite company saves countless innocent children's lives. The government saves a lot as well because of the present invention: saves by not having to pay the astronomical costs of disability and/or health care related to preventable injury or illness caused by harmful products, saves by not letting its companies go out of business or lose revenues due to publicly announced recalls, saves by preventing death of its people who are the actual generators of the wealth of the nation, saves by not having to spend with public announcements and advertising, but most important the government fulfills its primary and fundamental mission of preserving the lives and well-being of the nation and its people. As can be seen the present invention is extremely useful and vital not only for the user, but also the manufacturer and the government, and it is quite inexpensively implemented allowing the urgently needed wide spread coverage.

Considering the above example, since in this case, the recalled product is a level 4 (meaning a fatal event can occur with the use of the product according to the information from the CPSC) MrsLK20@hotmail.com is informed by not only electronic means but also conventional manner with autodialing, paging, and the like in order assure receipt of the critical information on this deadly crib. The system as will be further described may prevent even the death of the first

child, by informing the user about the risk before the government even issues a recall. In another embodiment, the GPI system uses a PCT arrangement which is a Public Computer Terminal, with bar code reading capabilities and connected to the GPI server and located in public places such as post-office, malls, grocery-stores and the like in which any user of a product, even if the user does not have a computer and/or is not a registered user, can send information to the GPI server concerning harmful effects of products being used. In this case the user may enter only the name of the product or the establishment delivering the product, but preferably the UPI which can be manually entered or scanned with the bar code reader. The user then fills out a simple standard form with type of effect B or H, and select from a menu of types of injuries/illnesses caused by the product, type of problem according to product, and the frequency of occurrence, and then the information is transmitted to the central GPI server. If a significant number of users report a harmful effect related to a certain product or establishment, said information is then transmitted to the FDA, CPSC computers or any other appropriate RIS computer. Naturally, anyone with access to the internet can transfer product warning information by logging on the GPI web site and filling out the product warning form. In the case of the deadly crib, if a certain number of users send warning identifying the crib as injuring, even if slightly, a child or having unsafe features as observed by the user, said information is transferred to all of the users of said crib as a GPI alert, not RIS alert, allowing the user to better evaluate the product and if applicable take the necessary precautions in order to keep the product from causing injury.

An alternative embodiment includes a personal acquired medical database which includes memory area# such as beneficial, harmful, recall and interaction data acquired that relates to the particular medical status of the user according to medical information and biological variables stored as well as any relevant past medical or allergy history. If for instance said user transfer blood glucose levels using the devices described by Abreu which indicates that this patient has diabetes, then all products stored in the product database for said user, and biological variables stored in the biological variables database for said user as well as all beneficial, harmful, recall, and interaction data for said user that relates meets the criteria "diabetes" are copied and stored in the personal acquired medical database under "diabetes". Thus, if the user wants to know what is product data, biological variables data, recall data, interaction data, harmful effects data, beneficial effects data that relates to said user's diabetes, said user can easily access the information which is stored under "diabetes" in the personal acquired medical information database. The user can also store any other personal medical information or acquired information in the acquired personal information database.

Alternatively also, the server memory also includes a Recall and Information Source (RIS) database in memory area #100 which stores the identifier for the actual sources from the recall and information source pool which provided UPI alert information to the GPI server.

LAST // It is understood that the transfer of data/information can be preferably done using conventional encrypted transmission in order to increase the level of confidentiality of the information. The central GPI server uses communications interface to communicate with a user and/or RIS with interfaces which supports standard or high-speed connections with the internet. The GPI server data to/from user and to/from RIS including exchange of messages with attachments such as files, video, graphics and audio are communicated in a variety of ways including a network interface electronically connected with commercial on-line providers, or configured as a web site, electronic mail address, worldwideweb interface, direct link, and the like along with other conventional physically wired and wireless communications and for the purpose of completeness conventional means as facsimile, postal mail, voice means, pagers, and the like. However, the preferred embodiment uses electronic means via a communications interface connected with the internet. It is also intended that conventional authentication means can be used in order to provide the authorized accessing of the GPI system. It is also understood that the database above described is only an illustrative system, and a variety of modifications, changes and database combinations can be made by those skilled in the art without departing

from the scope or principle of the invention.

In accordance with an exemplary embodiment of the present invention after the user acquires the unique product identifier for a drug said unique product identifier is electronically transmitted as a code over the network to the GPI server and then to the product database and drug memory area#. For instance drug "D1", "D2" and "D3" are stored in the product database in the DRUG memory area# with its respective users for said drugs. For example UPI 4546478 corresponds to D1 and is associated with Mr.ABC@mailcity.com , Mrs.DEF@whitehouse.gov and Dr.FGH@navy.mil. When a medical device "M1" is used, the individual unique product identifier UPI141618486 and respective user 15,976 is stored in the product database in the MEDICAL DEVICE memory area#. In this case as an example the IP address is assigned a unique user number. When the user Mrs.Ethel@gpi.co.uk transfer two different types of cosmetic "C5" and "C10", then the user Mrs.Ethel@gpi.co.uk appears associated with both "C5" and "C10" and stored in the product database COSMETIC in memory area#. When a baby product "B1" is used, the unique product identification code number is stored under product database BABY-TOY in memory area#, and when a food product "F32" is used its individual identification number is stored in product database "FOOD" in memory area#, and so forth with its associated usernames and representatives records. The GPI System can be used in a variety of environments, but since the drugs, medical devices, cosmetics, toy/baby products, and food are the main harmful products and recalled products, those are the ones referred in the description, however, this approach should not limit the invention to such products since virtually any product that could be recalled, the user can be identified, located and alerted by carrying out the principles of the present invention.

Besides the common products described above, a variety of biological data or biological states or biological function such as temperature, weight, visual acuity, blood pressure, eye pressure, blood glucose level and the like; or some common factors which alter said biological states can be used according to the invention such as; the implantation in living tissue of chemical substances, devices, artificial prosthesis, radio active seeds, and the like; the external placement on living tissue of devices such as hearing aids; the interaction of chemical compounds with living tissue such as cleaning and sterilizing substances; the manipulation or modification of living tissue such as with invasive surgical procedures and the like. It is also understood that any prosthesis, chemical substances, devices or the like will have appropriate identification number and codes which can be optically encoded for identification with subsequent acquisition by the IECLD and then the data on a particular medical device transmitted to the GPI server for storage in the database. For instance, if a certain type of prosthesis is later found to come from a lot which is contaminated, the patient would be sent a warning and instructions and how to proceed. The same would apply to defective material which could be found in intraocular lenses, defective circuits found in pacemakers, chemical substances implanted in the body such as altered silicone which was found to cause cancer, defective collagen implants used in cosmetic surgery which caused severe inflammation due to the material in that particular lot, defective sutures or staples used inside the body or outside the body which caused severe granulomatous reactions, stents used in vascular surgery that came from a particular lot and then later were found to easily crack and leak, defective X-rays and imaging devices which were used by a variety of patients and later found to have exposed said patients to a harmful amount of radiation, whitening gel coming from a tampered lot to be placed on teeth while sleeping which were found to cause severe allergic reactions and be caustic, cream for the treatment of skin disorders which were later found to cause permanent skin thickening and potential severe skin reactions, cosmetics which were later found to come from a contaminated lot and caused corneal ulcer and blindness, color additives which were later found to cause severe neurotoxic reactions, certain food from a certain lot which was found to be contaminated with E. coli and caused severe disease and even death, ineffective vaccines which were later found to come from a tampered lot, and the like. It is understood that any product that have a particular identification number could be optically encoded, tracked,

identified and located using the GPI System with the individual user being appropriately informed and instructed in regards to potential health hazard related to such product.

The GPI System allows patients to be continuously notified about side effects and interactions for immediate response and lifesaving precautions. The GPI System creates a completely reliable and updatable system allowing patients to take timely and appropriate action and not depend on the less reliable information by the health care provider or some times public news by the media in regards to harmful or recalled products. Since the IECLD is a portable device, patients could carry it while on a trip and remain informed as long as they have access to the GPI server. Patients could also have access to the GPI database via conventional communication means logging on the GPI server.

The user electronically communicates and send the information to the GPI server, preferably via the Internet logging on to the GPI server with said user sending the data on biological variables and appropriate code and password over the Internet to log said user into the GPI server. The GPI server allows many different users to access its resources at the same time. When using a web site supported by the GPI server, the user send its request on the product being used to said GPI server using a login name, which allows the user to remain anonymous, or alternatively whenever the user logs into the GPI server, all of the products with warning messages are automatically displayed in the computer system monitor and accessible to be retrieved by the user for more detailed information.

If for instance there is a request by the user, then the GPI server retrieves the information and sends the information requested about said product back to the user via the GPI web site or as an electronic mail message. As an illustration, the user sends its request by sending the information on using drug "X2", which is preferably optically encoded for acquisition and it is then transmitted to the GPI server and the GPI server analyzes the user code number, the unique product identifier code numbers, (such as bar code number for drug "X2") and password if present, and if there is any information related to said product or about the biological variables or related to factors which alter or interact with said product (drug "X2") present in the GPI database, then the login server instructs the GPI software to close the connection, retrieve the messages and/or Web pages stored in said GPI database concerning drug "X2" with said messages and/or Web pages being sent to the user according to said user code number (user of drug "X2") and internet address.

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All of the biological variables or factors which alter biological variables, eg. drugs, sent by the user to the GPI server are then subsequently stored in the GPI database under the code or IP address or domain name for said user allowing the information in regards to said user to be continuously updated by said user. If the user deletes for instance drug Y from the list of drugs being used, that information is sent to the GPI server which then will delete drug Y from the GPI database for said user, allowing the GPI server to continuously update the GPI database keeping track of new information which is added and old information that is deleted. For example, in another embodiment when a manufacturer of a pharmaceutical product or the FDA sends a warning to the GPI server about a product P, all of users of product P stored in the GPI database will receive said warning. When the user of product P logs in, the GPI web site, said user receives automatically the stored messages in the GPI database on product P, or alternatively when the user of product P logs in, said user is informed that there is a warning about product P stored in the GPI database which should be retrieved or there is an e-mail alert on product P that should be retrieved. In accordance, a duplex communication channel can be created in which the individual Mr.XYZ using product "P" automatically receives information related to product "P"

from the GIP server and the individual Mr.XYZ using product "P" can interrogate the GPI server in regards to any information which directly or indirectly relates to product "P" and that could have an effect on the health status of said Mr.XYZ with said Mr.XYZ having a coded identification number associated with his full internet address with said code identification number being used as a reference for storage of the products being used by Mr.XYZ. In this embodiment, the GPI System is used as a locator and information source which allows immediate delivery of information to individual using product "P". This invention is of extreme importance in the prevention of complications including death that can occur when using a variety of products including drugs in which the PRODUCT database of the GPI server continuously electronically receive information and updates in regard to product "P"" from for example the FDA or the company manufacturing product "P" or from any of the various RIS with said information and alerts being available to all individuals using said product "P". In case that post-market surveillance indicates a new side effect or new drug interaction, then all patients using drug "X2" for example, automatically receive information related to said update. The FDA or the pharmaceutical company manufacturing product "X2" could also access all of the patients anonymously, according to their internet address, who are taking drug "X2" and the appropriate warning being sent. The electronic automated location and information system of the present invention allows millions of users at risk of life-threatening event related to the unintended harmful effect of drugs and other consumer products, to simultaneously receive life-saving information in a free, timely, private, individual, confidential, orderly, precise, continuous, and cost-efficient manner.

In another exemplary embodiment shown in Fig.--, the IECLD is brought by the user to the point of prescription of the product, sale of the product, or receipt of the product. For example, the user will bring his/her IECLD to the pharmacy where said user is purchasing a variety of products including drugs. The user decided that he/she only wants to acquire information on the drugs and cosmetics being purchased, but not some consumable items as candy, milk, and other readily consumable food items and the invention thus allow the user to decide what products said user would be interested in receiving information and/or recall and/or alerts about the products being used. The user can simply only scan the products of his/her interest to be stored in the GPI server. On the other hand, if all of the products purchased are being scanned at the point-of-sale by a clerk, then applications can be used to select only relevant products to be transferred and/or stored in the GPI server. This manual selection or automatic selection of products to be stored is useful by avoiding excess of data being stored or useless data being stored. In an example for acquiring identification about a prescription drug for appetite control, the user brings his/her IECLD to the pharmacy. The pharmacy has a table with various UPI bar codes for each drug, or preferably each package will have the newly created UPI identifier bar code imprinted. The user enter his/her PIN or password, and then the unique barcode for the drug is read and the data is stored and displayed in the display of the IECLD. Alternatively, the user may access the GPI web site and enter the bar code number directly to the GPI server and database under the user's name. Alternatively the user may provide its code and enter his/her password and the data is sent directly by the point-of-sale (pharmacy) to the GPI server station to be stored under said username. Alternatively, during transaction and payment of goods, the bar code is scanned and the data is directly transmitted from the point-of-sale to the GPI server station via conventional or electronic communication lines. Alternatively the user may carry a smartcard which can acquire and store the product identification data for subsequent transmission of the product information to the main GPI server. In another alternative embodiment the users carries their smartcard consisting of a GPI smartcard which contains information on the user which identifies said user, and for instance when the user purchases a product such as drugs, at the point-of-sale during check out at the cashier, the GPI smartcard is entered or scanned, then products are scanned and the data on the drugs (or any products) being purchased is automatically transmitted from the point-of-transaction to the GPI server and stored

under the username of the GPI smart card. Alternatively the GPI smartcard is placed on a receptacle for acquisition of the unique product identifier codes with said user being able then to later select what products or group of products stored in the smartcard will be transferred to the GPI server for storage, allowing thus the user to select, and then transfer the data. It is intended that any physical data memory device besides a card can be used to acquire the product identifiers such as floppy disks, hard disks, optical disks, opto-magnetic disks, tapes, CDs, cartridges, semiconductor medium, and the like for later transmission to the server or to communicate with the server. Furthermore, any of the input/output devices can be connected to a printer for printing a list of the selected product identifiers transmitted.

The user of the GPI System can also interrogate the database which contains information related to the product being taken by the user which would allow the user to better and more safely utilize the product. The invention allows a very cost-efficient way of sending data using electronic information transfer. The GPI server electronically communicates with the government agencies and medical institutions in the U.S. and abroad as well as manufacturing companies which have information on products which are stored in the GPI database allowing up-to-the-minute updates in relation to potential hazardous situations involving said products. Government and private agencies and institutions send any relevant information to the GPI server or alternatively the GPI server actively searches for the information in the databases with the information about potential harmful products being then compared and matched to the current data stored in the GPI database and the user or users of that particular product being identified and whenever the FDA or the manufacturer issues any information, warnings, or life-threatening alert about a drug or product, bulk Web pages and bulk e-mail are sent by the GPI server to all of the users of the product related to the warning using conventional bulk mailing software with the lists of the user of the products being derived from the GPI database which in turn is the data transmitted by the plurality of users using the product, so appropriate measures can be taken by all of the users of said harmful product. All of the warning messages sent to the user includes detailed instruction on what to do and not to do concerning the product, Web site related to the product as well as address, and emergency phone number in case of life-threatening issues as well as information and/or guidance in regards to their medical condition and how to proceed including appointment scheduling and laboratory work-up. The user can also manually check and/or interrogate the GPI server for information in regards to warning messages which are stored in the GPI database as well as factors related to biological functions or factors which alter said biological functions which are being used and were transmitted to the GPI server by said GPI System user.

Fig.6 also show the various home-measuring devices such as self-tonometer to measure eye pressure at home as described by Abreu, non-invasive self-measurement of blood glucose as described in the prior art by Abreu, continuous temperature measuring device as described by Abreu, and conventional electronic blood pressure measuring device, and electronic scale. It is understood though that any other device capable of measuring any physical or chemical biological variable can be used in the present invention.

When the IECLD interfaces with the home-monitoring devices and a connection is established between the user and the GPI server, the user sends a list with all of the biological variables to the GPI server with the data acquired being transmitted to the GPI server and stored under the BIOLOGICAL VARIABLE (BV) database for that particular username. For instance if user Mr.XYZ has an eye pressure of 28, a blood pressure of 140/90, a blood sugar of 210, an average temperature of 98.6 F, and a weight of 250 lbs., then all of this data which is acquired from the home-monitoring devices (HMD) are then transmitted to the GPI server and stored under the BV database for Mr.XYZ with address Mr.XYZ@TYG.net The GPI server then checks to see if there is any message, warnings, information, recall or Web pages related to the products unique identification code or if there are any potential interaction between the biological variables stored and the products used by a particular username stored in the GPI database, with such

information as what biological variables that can interact with the effects of drugs, food, and the like, and vice-versa.

OPTICAL COUPLING /w Abreu devices: An optical transceiver mounted in the housing of the IECLD establishes communication with the various home-monitoring devices and receive and stores the information on the values of the many biological variables, such as eye pressure, blood glucose, temperature, blood pressure, weight, and the like. Data is transmitted and received by the microprocessor through the optical transceiver by conventional means of transmitting light signals. It is understood that the values of the biological variable can be manually entered into the IECLD or by RF transmission as described by Abreu, but a more cost-efficient system involves the optically automated transmission of the biological variables. The optical transceiver establishes data communication in bit serial format between the IECLD and the user computer system with said user computer system being connected to the GPI server. It is understood that the IECLD alternatively could act as the user computer system with direct connection between the IECLD with the GPI server without the need of the user computer system with said IECLD acquiring and transmitting to the GPI server both biological variables and product identification information. The acquisition, storage and transmission of data is performed via programming within the IECLD. USING WELL KNOWN TECNIQUES It is also understood that any means to transfer biological variables via a network such as the internet can be employed in the present invention with said biological variables being analyzed against the product identification stored in the database for the evaluation of potential interaction of the products with said biological variables.

With reference to Fig – LOGIC DIAGRAM - The user enter his password or PIN or biometric data into the IECLD (step 1). The password is stored in the microprocessor and compared with a corresponding password stored within another memory unit in the microprocessor. Once the password is validated, the user can enter data under said user's name. A variety of other means to ensure security and password systems are described in the prior art and can be used in the invention. If there is a positive match between the entered password and the stored password, (step 2) the microprocessor proceeds to the next operation, otherwise an alarm will sound informing the user that the password is invalid (step 3). As an example, drugs are being used. The user is now authorized to enter the data on the new drugs being prescribed via scanning the unique bar code identifier for the drug. The scanned unique UPI bar code number for the drug is then stored in the microprocessor memory for later transfer to the GPI server as described. The IECLD can interface with standard telephone lines using binary data with the binary data generated by the IECLD being processed via standard encryption application using conventional encryption algorithm available from the National Bureau of Standards. The encrypted binary data is then transmitted and demodulated and decrypted at the receiving unit with said unit being the GPI server computer station or another IECLD device. The GPI System thus allows secured communication not only between the GPI server computer station, but also between one IECLD and another suitable IECLD. The communication between two IECLDs would be useful if a patient with one IECLD wants to communicate and transmit the data on the drugs being used to a doctor who also has a IECLD, or to an insurance company which also has a IECLD, or to a hospital which also has a IECLD, or to an ambulance which carries a suitable corresponding IECLD and need to know precisely what drugs and devices a patient is using, or to another institution which may not have an IECLD but has means to access and decode the data being transmitted by the patient's IECLD, and the like. This allows the transmission of data in an accurate, time- and cost-efficient manner from one IECLD to a receiving point in need of that data. For the transmission of data between two IECLDs , the IECLD #1 is used in a barter way and IECLD#2 is programmed to accept data from another corresponding IECLD, such as IECLD #1, and the data is then electronically transferred directly between the two IECLDs. The responding unit such as the ambulance which carries a IECLD, may then automatically and

electronically receive the data from the patient's IECLD including the biological variables measured at home by said patient such as blood pressure, eye pressure, blood glucose, temperature etc, as well as the information on the products used and drugs and medical devices used. The ambulance IECLD can then send the information on the condition of the patient and treatment being administered back to the patient's IECLD for storage, and also to a receiving unit at a hospital which then will have all of the information on previous drugs and devices previously being used by the patient as well as biological variables measured at home plus the new information on treatment that was administered on the way to the hospital. For a complete and reliable information system to be implemented, in this embodiment it is preferred that the patient carry with him some type of identification informing that he has a IECLD and how to contact or access the patient's IECLD because sometimes a patient will suffer a heart attack or any other acute medical event and become unconscious with paramedics and physicians not being able not know what medications or devices is used by said patient. The knowledge of that information is sometimes the difference between life and death for that particular patient and the IECLD will provide the life-saving information in a timely inexpensively, and efficient manner. When for instance, the communication between the IECLD is established with the GPI server central computer station, the microprocessor is programmed to access and check the files and folders of the GPI database in the GPI server computer station after conventional data stream is exchanged and connection established between the IECLD and the GPI central server computer station. The IECLD then obtain any data on the drugs and products from the GPI server computer related to the drugs and products which are stored in the IECLD memory unit for the user, and said data is displayed in the display of the IECLD (step 7) with updating of the data stored in the IECLD memory unit with the new data being stored in said IECLD memory unit. If the new input data relates to drug "D" for instance which is given by the paramedics in the ambulance, the IECLD will send data informing the GPI server station that a particular patient Mr.XYZ was prescribed said drug "D", and the IECLD is programmed to obtain from the GPI server any information available on drug "D" or any information on interactions of drug "D" with biological variables of patient Mr.XYZ. So if there is new data, said new data on drug "D" will be displayed in the display, otherwise goes to step --- and end operation. If there is new data encoded with life-threatneing code, then a special alarm will sound to inform the user of the life-threatnening condition caused by the harmful product being bought or prescribed or given. If no new life-threatening code is present the microprocessor will continue to step – and display information. If a potential harmful product is identified and coded as harmful, the user is informed as well as the various point-of-sale carrying or selling said harmful product and doctors prescribing the harmful product are contacted, and a possible warning notice and information sent to said the numerous places and professionals described above.

ALTERNATIVE (bc-) Hand-held IECLD may also be used in an on-line manner using conventional communication lines such as telephone lines or electronic communications medium in which there is a link and transmission of data to and/or from the IECLD to the central GPI server computer station. The IECLD has data storage, processing and transmission capabilities and the on-line communication between the IECLD and the central GPI server can be done digitally using for instance an acoustic coupler. In this alternative embodiment, the coupling station is located at the doctor's office or at a pharmacy where the user receives or fill a prescription for the drug, or alternatively can be done by the patient at home. The patient enter a Personal Identification Number or password manually which is compared with a number stored in the IECLD memory unit. If there is a matching, the new drug can be scanned in using the bar code reader system and the data sent to the GPI server computer station using conventional communication lines. If at the time of entering, there is a warning about said drug stored in the IECLD, an alarm will sound and information stored in appear on the display. Although it is technically possible for the hand-held device to be updated with information from the GPI

Database at the time of the on-line coupling with GPI server computer station, this is not the preferred way since the hand-held device would have to have very large memory capabilities to be able to store the data on the thousands of drugs and/or products stored in the GPI database. When, however, the hand-held IECLD is used in this manner, any time a drug is entered, such as for instance scanning a bar code for that drug, said entered drug would automatically be evaluated against the data stored in the memory unit of the hand-held device. If the drug prescribed is found to have potential detrimental effects, an alarm would be activated and the information on said drug displayed in the display and a flashing light activated allowing immediate recognition of the potential harmful effect before the drug was even used or even purchased. Any time of coupling the new data is transferred from the GPI server station to the hand-held IECLD and vice-versa.

DESC. OF HOW TO USE. In accordance, in an exemplary embodiment, a patient is prescribed a drug called Dexfenfluramine (Redux®) as an appetite supressor. In this particular embodiment said patient enter his personal data and demographic data in his portable hand-held unit or alternatively said patient can enter the same data by using any personal computer system with said initial data consisting of a username and IP address or domain name. Please note that although the patient could enter his own name, it is preferable that said patient enter a pseudo-name in order for the medical information to remain confidential and not associated with the patient's real name, which is surely an advantage of the recall system as disclosed in the present invention which preferably uses the user's pseudo-name and internet address to inform said user about a recalled product that said user is utilizing. Thus, the invention allows the user to remain anonymous during the entire process of acquiring, transmitting and storing his medical data and then receiving the recall information. Thus the patient Mr. Gerald M. M. Jones enter his name as Mr.XYZ@GPI.org or Mr.XYZ@AOL.com or Mr.XYZ@Yale.edu and the like. Subsequent to that, the user, optionally, enter his age and other personal information as well as type of health plan and medical information such as related to pre-existing medical conditions and current medical therapy and/or medical diagnosis. It is understood that although the patient can input as much personal/ medical data as he wants, the system of the invention can be carried out, in the preferred embodiment, by simply having a username and IP address or domain name. In a preferred embodiment MR.XYZ also has means to acquire data related to his biological variables and/or home-monitoring devices and means to transmit the data to the main GPI server either directly from the home-monitoring devices or by using the portable hand-held unit which in a preferred embodiment acquires the signals from the various home-monitoring devices. Although the preferred embodiment uses biological variables acquired by home devices, it is understood that biological variables acquired in other places, other than the user's domicile, such as doctor's office, hospital, and the like, can be used with said data thus acquired and transmitted for storage in the main GPI server. Although the preferred embodiment uses acquisition, transmission, and storage of biological variables for the particular user, it is understood that the system of the invention can be carried out simply with the acquisition, transmission and storage of the products being utilized by said user. After the entering of personal/medical data, the user is requested to choose a PIN or password and login name, preferably the username for example Mr.XYZ, with all of the above information being stored in both the portable hand-held unit as well as transmitted for storage in the main GPI server creating a file for Mr.XYZ in the GPI database as Personal Information Database. Subsequent to that Mr.XYZ's system is ready to acquire, process, transmit and receive any data or information concerning products being used and/or biological variables being acquired according to the principles of the invention. In the preferred and exemplary embodiment, Mr.XYZ was prescribed Dexfenfluramine, and thus the Dexfenfluramine UPI, which uniquely identify that particular package and specific contents of that package, is acquired by reading said bar code symbology with bar code reader of the IECLD. The data acquired by the portable hand-held unit is then transferred to Mr.XYZ computer system which in turn is connected to the internet and the data further transmitted to the main GPI server for

storage as for instance under Mr.XYZ@GPI.org with the DRUG database having file Dexfenfluramine and/or code 090911919. Although the use of optically encoded symbology provides the most time-efficient, orderly and virtually error-free system as used in the preferred embodiment, it is understood that the user can enter and transmit this data in a variety of ways including wireless acquisition and transmission, keyboard entry, physically wired connection, and the like. In some cases the user of the product can use the serial number of the product which is already in the package and manually enter the data into a conventional computer system for transmission to the GPI server. Let's assume now that Mr.XYZ moved to another state or country and has about a year supply of his Dexfenfluramine, or in another scenario Mr.XYZ will be on a trip abroad for the next 4 months. Suddenly, during post-market surveillance, the FDA uncovers potentially fatal adverse reactions caused by this drug Dexfenfluramine (Redux®) and issues a recall. The drugs from the pharmacies are recalled, but the ones already being used are still out there being used by millions of patients across the world. Expensive printed matter to health care providers and institutions are distributed, but there are no current means in the prior art to address and identify the actual individual unique user of the product, and thus unfortunately the actual user cannot be directly addressed and is at risk of injury/illness and death. Many times public announcement recall through media is used in order to alert patients to stop using the drug with the dire financial consequences to the manufacturer and distributor which now have to go public and basically say "Sorry, we made a product that kills and harms people". Unfortunately, publicly announced recalls means economic death and sometimes bankruptcy to many companies with the consequent laying off hundreds of employees, and thus it is easy to see the devastating consequences to companies issuing public recalls and for the economy of the nation in general. Furthermore, this system is quite ineffective and neither identify the individual user nor identifies all the users of the product, as we saw with the deadly crib situation previously described in the background. With the present invention, as soon as the FDA issues even a warning or a recall for the drug Dexfenfluramine, said recall information is immediately and preferably electronically transmitted to or acquired by the main GPI server as Dexfenfluramine code 090911919, and the GPI server automatically stores the recall information acquired in the recall area#. Each time the server receives product information, the server checks its database for users of said product. In the case described on recall of Dexfenfuramine, the server searches its database to identify all users of Dexfenfluramine code 090911919, and after the users are identified, the recall notice is INSTANTANEOUSLY AUTOMATICALLY electronically and PRIVATELY sent to ALL users of the drug alerting about the fatal risk involved with the use of the drug with said electronically transmission preferably done using conventional bulk e-mail software. The system of the invention can then TIMELY locate and alert all of the users regardless of their physical address or even if the user has moved and/or is lost to medical follow-up by using immediate electronic transmission of information. The system also provide, thus, means to locate each user INDIVIDUALLY by using an exclusive unique name and address, as the internet address. The real name of the user of the drug remain CONFIDENTIAL and the name of the company with the recalled product has minimal public exposure and privately can address the users of the recalled product and thus preserve the company's name. There is a critical need of ensuring confidentiality of the user of the recalled product as well as to protect the company recalling the product from unnecessary media exposure and the system of the invention assures the confidentiality and protection of the information by using electronic private transmission and receiving of the information. It is also important that the confidentiality and security be achieved reliably, efficiently and with minimum cost and effort which is accomplished with the system of the invention since acquiring, storing and transmitting binary data is easier and far low cost compared with other non-electronic means. Now, if we go back to our patient Mr.XYZ one can notice that he is travelling abroad and has basically no means to know about the recall in his country of origin. However, Mr.XYZ can have continuous access about recalled products that he is using by either using his portable hand-held IECLD unit with connection to the internet or has

means to connect to the internet with conventional computer terminals, and then as soon as Mr.XYZ either checks his regular e-mail; or web-based GPI site e-mail; or logs in the GPI website and enter his password, the information on the recalled drugs that Mr.XYZ are using are disclosed and displayed in the display. The GPI System then allows any remote user to access the information on potentially harmful products being used by said user. Besides warning about the fatal risk with the drug, the system also instructs the patient on how to proceed. In this case a particular formulation of the drug-type Dexfenfluramine was later found out, after almost 2 years in the market, to cause severe and potentially fatal heart disease by affecting the valves of the heart. In response to that, the GPI System instructs the patient about the alternative products for his condition, actions to be taken including how to stop the drug and the need to see a heart specialist and to have an echocardiogram done with the GPI system automatically contacting the patient health care provider and scheduling an appointment, and contacting the hospital and laboratory and scheduling the test (echocardiogram), and contacting the patient's health plan for approval if needed for the tests and appointments providing thus a complete and efficient and low-cost comprehensive prevention and treatment of illness/injury caused by a harmful product. Furthermore Mr.XYZ will have an option to fill out an electronic questionnaire about cardiopulmonary symptoms and other symptoms in order to better assess the level of urgency for medical therapy since Mr.XYZ is travelling abroad. The present invention also provides a complete set of instructions according to official and medical recommendations such as the need for antibiotic prophylaxis when Mr.XYZ undergoes a dental or medical procedure in case he has the heart valve disease caused by the harmful drug.

The GPI System will have the ability to continuously locate a patient and warn said patient about potential problems with the products they are using. For instance some times a patient will have implants permanently placed inside of their bodies and are lost to follow-up without the doctor being able to locate said patient and inform about the complications related to the product being used or implanted. Even if the patient moves, change addresses, or is unable to be reached; an update about the prosthesis permanently implanted could be sent to said patient as long as they have their IECLD. If the patient has access to the internet and knows the UPI code number or name of the product, then the data can be entered using a keyboard and the patient access its GPI server file or general recall information at the GPI web site. Patients usually carry a card regarding the number of the prosthesis which was implanted and can check the information related to said prosthesis. The same also would apply for patients receiving living issues such as kidney transplant or any other type of transplant. If the subject who donated the organ was later identified as having a transmissible disorder such as viral disorders, the recipient of the organ could be notified and instructed in how to proceed even if after many years after the operation in the same fashion as described above. A real example occurred with the use of dura (a membrane in the brain) which caused a potentially fatal encephalitis. It was difficult to locate all of the patietns which received dura from that particular contaminated lot. However, with the system of the invention any patient who received the graft dura can easily access the databse by logging in the GPI web site and found out the information, or if the user is registered with the GPI server the warning information is delivered to the user as soon as it is received. If the user is buying or using a product which does not have a UPI, the user can enter the name of the product and if a recall notice is issued for that product, the GPI system will match the name against its database and identify the product with the consequent recall alert sent to all of the users of said product. If for instance the user is buying products in the internet, then the product purchased can be transmitted to the GPI server using conventional applications. For example, a vitamin sold in the internet is being recalled because it has severe complications including death of the user. An user of the system could before actually purchasing the product send the information to the GPI server which will return any recall or information available on said product preventing thus the user from wasting money and risking his/her health by alerting the user before said user purchase the

product. Although, the system is being described concerning human use, it is understood that veterinary and other non-human use is another alternative application of the current invention.

HTML documents and HTTP

One aspect of the invention provides a system composed of HTML documents and information transfer using Hyper Text Transfer Protocol. Although the exemplary embodiment uses data communication using HTTP, other protocols such as FTP, Gopher, and other emerging protocols can be used as means to transfer recall and information data on particular products being used by a particular user and biological variables for said user. Although the exemplary embodiment uses HTML documents, it is understood that any other type of documents can be used including but not limited to Adobe PDF, motion pictures, still pictures, voice or any other means related to provision of information about potentially harmful or beneficial products, recall and interaction information. Fig --- shows electronic information converted to HTML document depicting an exemplary home web page for the GPI Recall, Location and Information System as it appears on a computer system display screen or a portable hand-held as the IECLD device with internet and HTML capabilities. A secured page GPI Products Alert/Recall (accessed only by the user of products presented in said page, after appropriate identification is confirmed) is showed with the information on products used, biological variables, and information on recall and alerts (harmful and beneficial) about the various products used by said user and associated hyperlinks displayed in the document. To illustrate in more detail this particular document, the Products Alert/Recall document shows a box with the itemized product groups being used by Mr.XYZ which can be individually accessed by point-and-click. A second box in the same document shows the current information on recall or warnings for the products used by Mr.XYZ with the product name and group in one column and the information about the product in a second column, all of which accessible by point-and-click. In Fig ---a portion of the secured document Biological Variables for the particular user is shown with the values measured and the links to the various potential interactions of products being used with said biological variables measured. A portion of the page Recall Info shows text and HyperText illustrative of recall of a certain drug with links to documents relevant to said recall, to the manufacturer, to the recall government agency, and links to support groups, information on the medical condition, how to get a doctor's appointment (with both doctor's located in brick-and-mortar offices or internet offices) and scheduling of laboratory test (echocardiogram) and insurance information. The portion of the document Recall Info also has links for registered users to access personal and confidential information such as the doctor's appointment already scheduled, the echocardiogram already scheduled, and the insurance approval for the test already obtained. Please note that the registered user can access the personal and private information on products used which are recalled in different ways. One preferred way includes the user checking his/her GPI web-based e-mail, and in this case the user will receives in his/her e-mail box all of the secured pages related to warning and recalled products such as GPI Alert/Recall document, Biological Variables document, Recall Info document , appointment and insurance information, and the like. Another way is for the user to log into the GPI web site and with his/her password access the same personal/private information, as described above, on products being used and alert/recall information on these products. A further way to retrieve the personal/private alert/recall information is by reading his/her conventional text e-mail messages. Please also note that the information on products used and personal appointment information is in a secured area are accessible only by the user of the products. Alternatively, the page Search and Recall Info are non-secured documents and can be accessed by anyone simply by log into the GPI web site allowing anyone to freely access recall and warning information on any particular product being used by the user logging into the GPI web site. Thus, GPI System provides a free service to both registered and non-registered users, but the registered user does not have to search for recalled products or warning or information on products being used, since the GPI System

delivers to the individual registered user given IP address or domain name all of the specific information on harmful products that are used by said individual user with all of the other numerous additional advantages such as information on beneficial effects of products being used and other benefits as described in this current patent document in accordance with the principles of the present invention.

The system does help companies to have the least amount of exposure with avoidance of the financial disaster that occurs to companies which have to rely on publicly announced recalls through the media as previously explained in the background and above. Moreover, the companies and government agencies save considerable amount with recall and warning about potentially harmful products since is extremely expensive to use conventional printed, televised and audio media to cover the whole country and in most cases the world, and still not reach all of the users. Sometimes, as can be seen with the deadly crib, companies and even government agencies have to run adds, videos, e-mails and so forth several times during the year for each product, but it is still quite inefficient as the number of recalled products barely reaches 15% as with the deadly crib which continues to kill and harm innocent toddlers. It is also easy to see that companies will be more encouraged to implement recall programs in large scale if companies can privately and individually identify and locate the users of the recalled products. It is easy to see the devastating financial consequences to a company which have to rely on conventional recall if 2 products of the same company cause potential unintended harmful effects. Sometimes the product is not recalled but only a warning is issued, but considering the above difficulties and limitations said warnings rarely reach the user until said user suffer the harm caused by the product. Since the principle of the invention also includes disclosure of potential unintended additional benefits that the product can provide, the user can take full advantage of all of the benefits of using said product. Companies most of the time do not disclose newly found potential benefits because it is quite expensive to spread the information throughout the whole country with the very expensive conventional media means. The system of the invention searches and/or acquires data from the various RIS not only about the harmful effects of products, but also the newly found beneficial effects of products. For instance the document Alert/Recall shows in the product column D1 – "Verapamil" and under information "beneficial". In this particular case, a Research Institution and a Medical Institution of the various RIS transferred information that verapamil was found to decrease eye pressure. This patient has hypertension and is using this drug verapamil to treat his hypertension. This patient also has abnormal and elevated eye pressure. The information transferred on verapamil as decreasing eye pressure is checked against the users' database, and since this user has glaucoma with increased eye pressure, the interaction product-biological variables is considered beneficial and the information is transmitted back to the user as previously described. In another example, a patient is using some type of birth control pill and new research found out that the hormones present in that particular pill formulation decreases the risk for breast cancer. This information could be quite important, if for instance the patient has a family history of breast cancer, said patient should consider remaining on the pill instead of using other contraceptive means. The registered user of the products could log onto the GPI website and check any beneficial information related to the products being used, in the same manner as to check for the harmful or recall information.

Fig – also shows the GPI home page linked to the GPI AlertRecall page by means of link – which in turn is linked to document Biological variables by link--. Document GPI Alert/Recall is also linked to page Recall Info by means of link --. Home page GPI is linked to Search page by means of link --, which in turn is linked to page Recall info by link--. Although the links shown relates to text document only, it is understood that images, videos, sound, programs or any binary data link can be implemented and used as for example the HyperText surgical correction can be linked to an actual video of a heart surgery with valve replacement, which gives more information for the user of recalled products while allowing said users to seek immediate therapy and better evaluate all of the potential aspects related to the delivery of health care for his/her medical

condition. It can be easily appreciated that the principles disclosed in this section can be applied to any product including but not limited to the main product groups (drugs, cosmetics, food, medical devices, toys/baby products, and miscellaneous) and the user informed about the potential hazards and recalls associated with the products being used. It is clearly also noted that the figures presented are simply a way to illustratively describe one of the embodiments of the present invention, but obviously there are numerous other ways to display and deliver the information and many variations all of which can be used in the present invention. Also in accordance with the principles of the present invention, user applications such as a web browser can set up a connection to the remote GPI server in order to retrieve the information on potentially harmful products that is requested by a user, and as an example a user browser application display a hyperlink associated with documents related to the recall/warning and information system, for a unique user, which can be selected with another document being retrieved over the internet from the GPI server in which case said GPI server acts as a HTTP server. It is understood though, that the present invention can be employed with other types of user and GPI server applications any of which allowing access to certain sources and certain data over the internet with said data and/or sources relating to harmful/beneficial products and/or recall/warning information. It is also understood that the user and server computing systems according to the present invention can include a variety of operating systems and commercial applications to assist the implementation of the needed acquisition and transfer of information related to the potentially harmful products with creation and transmission of messages.

Another real life example will demonstrate how to fully use the present invention and the need for the technology in order to reduce the alarming number of harmful events caused by a variety of products. The real example involves a shampoo to treat dandruff which was later found to cause fatal reactions, blindness, diabetes, and other severe complications due to some of the ingredients present in its composition. Since this product was being sold over the counter without the need for a prescription there is no way to identify who is using this extremely dangerous shampoo which has been recalled and removed from the market. After being in the market and widely sold, it was later discovered that this shampoo contained a large amount of a potent corticosteroid in its composition which can cause a fatal reaction in some patients and overall significant amount of complications and illnesses for the majority of the users. In this case, using the present invention all of the users of the shampoo would be informed about said harmful product in the same manner as described above. Thus the user in this case Mrs. Jane M. M. Jones, username Mrs.XYZ and address Mrs.XYZ@GPI.org uses her IECLD and chooses the key cosmetics in the keypad of the hand-held portable IECLD and product UPI for the shampoo is entered using the bar code reader and the data transmitted to the main GPI server in the fashion already described. The shampoo was later found to have substantial amounts of a potent steroid which could cause severe complications and even death in some patients. Sometimes shampoos come in large containers, as was with the case presented, and sometimes patients get a discount by buying two units. In any case, without the current invention Mrs.XYZ would continue to use the shampoo even after the shampoo is identified as harmful since there is currently no way to identify and locate the users of a particular product. However, with the current invention as soon as the recall is issued a message is sent to the user to "stop using this shampoo immediately" and other messages/information/instructions according to the preferred embodiment of the invention. Alternatively the present invention can be carried out by Mrs.XYZ providing a GPI card consisting of a GPI smartcard which contains the information on Mrs.XYZ with said card being entered by standard means, and then the information on drugs and cosmetics for example which are coded as such will be identified at the point-of-transaction during scanning of the bar code and automatically transmitted to the main GPI server. In order to prevent misuse of the GPI smartcard, a PIN can be entered by the user before any data on the card or opening of connection with the GPI server can be accessed. Alternatively the IECLD can be placed in a cradle and the

data which is scanned at the point-of-transaction is automatically transferred to the IECLD and stored for further transmission to the main GPI server at the user's domicile. As soon as the data on the product is transmitted if there is a recall or warning an alert signal and light will be activated and the information displayed in the display. When a certain food product is entered which interacts with the drugs stored in the GPI database for said username, then for example when cheese or wine is acquired and UPI or name for wine and cheese is transmitted, the information is checked against the drugs being used and if the user has in his/her database drugs such as MonoAminoOxidase inhibitors, then the system informs the user of the potential interaction and harmful effects of that particular drug-food combination and also return to the user alternatives to said food and display the information on the display, either the IECLD or the user's computer system with said display occurring at the point-of-transaction or later retrieved by the user. The same would apply if a patient start using a known non-recalled typical low-potency steroid cream, but then later the patient acquires a biological variable concerning blood glucose using the device by Abreu with said blood glucose level being elevated, then the recently acquired data on the elevated blood sugar is checked against the drugs and products in the user's database, and the steroid cream is identified as potential harmful interaction with said biological variable elevated blood sugar and the information is returned to the patient in the manners previously described. Thus, the user does not need to know what is in the label or the ingredients of the product or the relationship of the product to his health status and other drugs being used because the GPI system will evaluate and provide the necessary information to the patient. As a further example demonstrates how to use the invention, a laxative was later discovered to potentially cause cancer. The patient using the laxative will again be notified of the side effect as soon as the information is received, even if only as a warning, since the information was received and/or acquired from a research institution and from published information in medical journals. The system thus allows the user to evaluate the possible harmful consequences before the drug is even recalled by the FDA or any proven damage has occurred. The drug in this case was later found to indeed be related to the development of tumors and was recalled. In other cases the system may alert the individual to undergo a certain test since a drug to treat diabetes was later found to have effects on the liver. In this particular case the system will inform the user of the drug about the recommendation to check liver enzymes, and will automatically schedule an appointment, laboratory testing for the liver enzymes, and insurance approval if needed, for all the registered users of said drug. Besides informing the user about the harmful effects of products, the GPI system also informs the user about the potential beneficial effects of the products being used. Thus, for instance, if Mrs.XYZ has stored in the GPI database age of 50 and using estrogen replacement, the GPI System identifies that association as a positive one since said GPI system received information from the RIS informing that estrogen use in post-menopausal women reduces death from cardiovascular disease, and then said information is electronically returned to the user Mr.XYZ and displayed in the IECLD or the user's computer system or accessible for retrieval at a later time. Thus, Mrs.XYZ can privately and individually receive the information on beneficial aspects of the products being used. In case a different hormonal replacement therapy had been instituted, the GPI system will inform the user about the positive effect of using estrogen or if a harmful effect or interaction is found the user is informed in the same manner educating the user about what hormonal replacement may be harmful or beneficial. In another embodiment, if the user has stored in his/her personal information database medical data indicating that the user has family history of Alzheimer disease, then when information about a drug that help Alzheimer is transferred from the RIS, this data is checked and Alzheimer identified and the information is sent. In this case the information may read "low doses of risperidone, regularly prescribed for schizophrenia was found to help relieve symptoms in Alzheimer's patients and thus reduce the burden for caregivers and be a cost savings by delaying hospitalization. Please consult your doctor." In this instance, although the user does not have Alzheimer, since in his/her database has a family history of the disease the information is sent

which allows the user to better care for his family members. This information could also be useful to the doctor who may not be aware, and said information being conveyed to the doctor's relative by the user. If the user for instance enter in his/her database sleeping difficulties or insomnia, that data is checked against the patient database and all products which may decrease sleep or promote sleep are identified and the user informed. If the user has in his/her database drugs related to sleeping disorders, any information from any of the various RIS concerning sleep is transferred to the user. Moreover, if later on information on a new herbal medicine is found to promote sleep, then that said beneficial information is sent to the user, and if approved by the user and user's doctor, the same information is electronically sent to the user's doctor 2 days prior to the user's appointment, so said user can discuss with the doctor the information and the doctor can do a survey to find out more about the drug before the patient's appointment. Naturally all of the user's biological variables could also be sent allowing the doctor to quickly and efficiently, looking at only one printed page, evaluate the current health status of the scheduled patient and answer questions said patient/user may have when coming to the appoitment.

Although the IECLD is preferably designed to be used by one person, more than one user can have his/her individual database in the microprocessor-based IECLD. Naturally the user can select what are the products or type of products said user is interested in receiving recall or warning information, and thus if the user does not purchase or use baby products, said user has the option of not acquiring the information or/and not transmitting the information and/or selecting not to receive recall/warnings on the particular product. The user can at its sole discretion cancel or add any products or group of products to the main GPI database at any time. Besides the user actively deleting items, the principle of the invention also includes an expiration date for some of the products entered such as perishables and ready-to-consume items as certain foods, cosmetics, and so on, so as the stored database for the user does not grow too large and products would not be kept around in the database of the user for a long time.

However, users continue to perish and suffer since they did not have access to the information.

Another embodiment relates to use of the system not only by patients, but also doctors, medical institutions, and the like. In an exemplary embodiment, doctors who prescribed certain drugs and medical institutions which use certain coded devices could easily acquire the unique UPI for the drug or device and send said unique UPIs to the GPI server allowing the doctors and medical institutions to have an updated information in regards to the products being used by said practitioners and/or institutions. Furthermore, although the present invention can be preferably used by an individual user of a certain product, alternatively the current invention can be used by the provider prescribing the product or the institution delivering health care or the establishment selling the product. In this alternative embodiment the hospital, providers, establishments, seller, distributor, and the like send the information on the products to the GPI server and receive feedback specifically tailored to the products being used or delivered or sold by said practitioners and establishments. For example if a doctor prescribes risperidone on a daily basis, then said doctor have stored in his/her database products used which actually mean products prescribed, and then when new information related to risperidone such as beneficial effects, harmful effects , and recall would be automatically electronically sent to the doctor. Naturally, the same information and updates would apply to all of the commonly used prescribed drugs by the doctor which are stored in the drug product database. Then, when the information from research indicates that risperidone may help alleviate symptoms in Alzheimer's patients, the doctor can use that information to better treat his patients. Physicians usually are flooded with information receiving over 10 medical journals or publications a month, and is very difficult to sort through this vast material and identify issues and facts that could be applicable to each doctor's individual

practice, and thus this alternative embodiment is an incredibly useful tool for any doctor helping to deliver the specific information that the practitioner needs according to his practice and prescription patterns. In this case the doctor could have 2 registered names Dr.X20@GPI.org in which the user/doctor store in the drug product database the names of drugs commonly prescribed, and then have another registered name Mr.X20@GPI.org in which said doctor store in the drug product database his personal list of drugs being used, thus allowing the GPI system to meet both personal as well as professional needs of the user. This same alternative embodiment could be used by a merchant or medical institution interested in knowing updates and information about a particular group of products being sold or delivered. In an exemplary embodiment, a restaurant serving fish will have in the products database Food the types of fish being used by said restaurant, and then if any of the RIS send information that for example stating "cod found to decrease blood pressure", then that information could be used for the benefit of the customers eating at that restaurant and disclosed in the menu that according to source University of USA cod was found to reduce blood pressure. The customer then with high blood pressure can make an educated choice concerning his/her health and choose cod. On the other hand, the customer with low blood pressure can make an educated and healthy choice of not eating cod since that could aggravate his/her status, potentially leading to lower pressure, dizziness, and even a car accident due to the exceedingly low blood pressure. In another exemplary embodiment, a farmer using a certain fertilizer will have in the product database Miscellaneous a memory area for chemicals, or alternatively the drug area memory can be used as chemicals and drugs, and then if any of the RIS provides information concerning the type of fertilizer used and stating "fertilizer FZ found to be mostly beneficial in crops, such as corn, and actually detrimental to wheat. In this case the farmer then can use the information to optimize production since the GPI System delivered valuable information for increasing crop production specifically tailored to that individual user. Since the GPI only uses well-founded and proven information and data from well recognized established government and private institutions, the information acquired from the RIS can be considered sound and valid, and thus very useful. Although, the preferred embodiment includes tangible items, any other non-tangible items can be included as a further embodiment will illustrate. If a software product that is uniquely identified with a code or its name is transferred to the GPI database by a registered user said code or name is stored in the Miscellaneous database in memory area#, then the registered users of said products, according to their preference, will receive updates tailored to the products stored under their username, such as but not limited to, software downloads and updates related to the product stored in the GPI database, links to software and/or internet resources related to the product stored in the GPI database, and the like. For the sake of clarification and completeness of the description a further embodiment will be described. If a chemistry book is purchased by a user in Japan and the book identifier is stored in the GPI database, and the GPI server later receives warning information on said book, then the GPI server send the warning message to the user for example stating that due to a printing mistake, the combination proposed for experiment 12 on pages 20 to 22 may pose a hazard, please refer to the enclosed information for the correct sequence and correct compounds for the experiment. Moreover, if the same user in Japan who transferred the book UPI, also transferred to a subject database in the GPI server the unique identifier "x-ray ultra absorption spectroscopy" or "XUAS", and if the GPI server in the US acquires or receives information about the above subject identifier from the German Federal Institute for Drugs and Medical Devices stating that it was found that the above "XUAS" technique is exposing researchers to dangerous levels of radiation, then the information is transferred to the user in Japan accordingly. Although, only few exemplary alternative embodiments are disclosed, it is intended that the current invention can be used with any product, subjects, articles, and the like, tangible or non-tangible items, which has an identifier indicia, belonging to or, delivered or acquired by any individual, establishment, entities, and the like with data and information preferably transmitted via the internet.

Furthermore if a user brings his/her IECLD to the doctor's office the drug being prescribed could be entered and if there is a medical reason for the drug not to be prescribed or a drug interaction, then an alert will be displayed in the display and the doctor can find an alternative before the patient buy or start using the drug. For example, if a general practitioner is prescribing a drug to control heart rhythm such as amiodarone, and if the patient has stored in his IECLD his medical information which includes measurement of his biological variables, and if the patient has stored his eye pressure which for instance was elevated which put said patient at risk for optic nerve injury, and considering that amiodarone was recently found to cause optic neuropathy as an adverse reaction, then the system identifies the potential harmful interaction between the drug being prescribed and the biological variable measured and alert the user and the doctors. Naturally the patient also could be made aware of the harmful interaction at the point-of-sale, in the pharmacy by sending the information to the GPI server, or at home by uploading the information to the GPI server and thus receiving the warning. The system also will give the alternative medication or procedure that can replace the one prescribed and that does not have negative effect for instance in the optic nerve or in patients with increased intraocular pressure. Although, the preferred embodiment involves use in the doctor's office, the methods and apparatus of the current invention can be used in any environment and it is intended not to be limited to health care environment only.

LOGIC FOR USER. As described in figure --, In reference to fig --- there is shown a flow chart of an exemplary data acquisition procedure in the current invention by the portable IECLD, and with options for subsequent transmission of data. The illustrative steps depicted refers to a preferred embodiment where the user acquires optically encoded unique product identifiers using a bar code reader mounted in a portable hand-held programmable microprocessor such as for instance the IECLD. It is intended that other manual or automatic means of acquiring the unique product identifier can be used, such as manual keyboard entry, verbal entry, RF, optical, satellite, cable, telephone lines as well as any other wired or wireless means. It is easily appreciated by one skilled in the art that the user can enter and transfer unique product identifiers using standard computer systems previously described and thus bypassing the IECLD. The GPI system can also work using different links such as on-line connection, off-line connection, direct link, and the like, and the few following examples will better demonstrate the options. For instance the user transfer UPI and remain connected with the GPI server receiving immediate product recall/information feedback, or the user send the UPI and biological variables, and then disconnects from the GPI server. As another example,the user remain on-line but there is no information in the GPI server for said UPI transmitted by the user, then the user disconnects and in this later case as soon as the information on said UPI is transferred to the GPI server by the RIS, said recall/product information is transmitted to the user which may be connected or disconnected to the GPI server. Alternatively, the user may only receive information by conventional e-mail from the GPI server after transmitting biological variables and/or UPIs, and so on. In the exemplary embodiment of Fig---, when the user activates the IECLD, then the IECLD prompts the user to enter his password or PIN or biometric elements (step 1). The password or biometric elements is stored in the IECLD microprocessor and compared with a corresponding password/biometric elements stored within another memory unit in the microprocessor. Once the password/biometric elements is validated, the user can enter the unique product identifiers under said user's name. It is understood that a variety of other means to ensure security and password systems are described in the prior art and can be used in the invention. If there is a positive match between the entered password/biometric elements and the stored password/biometric elements, (step 2) the microprocessor proceeds to the next operation and enable the keypad and/or bar code scanner, otherwise an alarm will sound informing the user that

the password is invalid (step 3). The user is then prompt to enter product group using the keypad at step---. The user is now authorized to enter the unique identifiers of the new products being used via scanning the unique bar code identifier at step---. The scanned unique bar code number for the product is then stored in the IECLD microprocessor memory. The bar code identifier number of the scanned products are then displayed in the display of the IECLD. If the IECLD's memory has stored the name equivalent of the products (in this case the name of products mostly used by the user with its bar code identifier can be stored in the IECLD's memory unit) which correspond to the bar code scanned, then the unique name and/or characteristics of the product will be displayed, otherwise it will end the operation for acquisition and storage of unique identifiers of products. The user can later then identify and select the products to be transferred to the GPI server database, or the user can later transfer all of the product identifiers scanned into the GPI's server database under the user's name using his/her personal computer at home or transfer directly from the IECLD to the GPI server. Alternatively, if for instance the point-of-transaction have means to connect to the GPI server, the user can use the GPI smartcard by manual entry of numbers or preferably by swiping the GPI smartcard through a reader and have the transfer of unique product identifiers take place without the need for duplicating the reading of the bar code, so all of the product identifiers being scanned are automatically transferred to the GPI server according a criteria set forth for each individual user. In fig – the alternative embodiment using a smartcard is shown in more detail, at the point-of-transaction the user may acquire a variety of UPIs and then the user swipe the smartcard through the reader. The smartcard has memory medium with the user identification and encoded data that opens a connection with the central GPI server. The point-of-transaction has a card reader communicating with the GPI server. When the UPIs code are scanned using a conventional bar code reader at the point-of transaction, the UPI data is automatically transferred to the GPI server and stored under said username (**FIG**). Although, the point-of-transaction can have means to select what products to select and transfer data on, in most case it only would be cost-effective if all products or at least all products of a certain group which were identified by proper code be sent to the GPI server. If all products purchased by every user are scanned and the data transferred to the GPI server it could create a potential data overload. It is preferred that the user has the option to select the products that should be transferred and stored in the GPI database, and most likely the products that cause significant harm and increased health care costs. Although technically possible, it would be difficult if for example, at the point-of-transaction user Mr.RS only wants one item transferred, then user Mrs.ST wants one item form the D2 (OTC drugs) group and 4 items of the C (cosmetics), and none on the F (food) group, and then another user Dr.TU purchase items in all of the groups but want 2 individual products of the Mi (Miscellaneous) group, 1 out of 10 in the F group, 2 out of eight in the C group and so forth. It is easy to see that it would be possible, but difficult to implement the invention in that fashion. It is, thus most preferable that the user transfer all of the identifiers or select only the products interested in receiving information on by acquiring UPI with the IECLD only in said selected items. Alternatively the user can acquire data on all the products purchased at the point-of-transaction which are stored in the smartcard with said smartcard later being read in a suitable reader and the items selected by the user and transferred to the GPI server for storage. Naturally, the user during registration or at any time thereafter has the option to select and/or block the information to be sent about harmful, benficial, or recalled products at the user's discretion. For example, the user may only wants to know about recalled products, or only recalled drugs and harmful effects of drugs, or recalls and beneficial information on cosmetics, or recalled baby/toy products and recalled drugs and cosmetics, and so on. So, even if all UPIs are transferred the system can be tailored to the individual need of each user and thus only transfer meaningful data to the user.

Naturally the DML user block the warning messages and pages at their discretion

LOGIC TRANSFER Referring now to fig 12 there is shown the steps and flow chart related to the transferring of unique product identifiers with the user first initiating standard wireless or wired transfer of information from the hand-held portable IECLD to a computer system with said computer system then automatically initiating a call to the GPI server with connection established preferably over a packet-switched network or alternatively over conventional communications medium. The user is then prompted for username (preferably the IP address or domain name in this case) and password at step..... The user then enters his username and password into a keyboard of the computer system in the standard manner at step..... The user identification data is then communicated to the GPI server and if there is a valid username and password in the user information database, then computer proceeds to next step, otherwise prompts the user for registration with the central GPI server at step.... The unique product identifiers are then transferred to the central GPI server at step.... with said central GPI server then checking the product database to determine whether this unique product identifier is a new product at step.... If not then a new file for the product code is created and the database updated to reflect the new unique product identifier at step... Otherwise it proceed to the next step and the central GPI server determine whether if there are any biological variables, and if there are then the biological variables database is updated to reflect the new data at step... otherwise proceeds to the next step. The GPI server then **engage a search engine and** sorts through all of the product information in the GPI server database at step.... to determine if there is any warnings or recall information related to the UPI transmitted. The product information may be separated by type of effects such as beneficial, harmful or recall. The Alert database maintains a record of the beneficial, harmful, and recall information for the various UPIs with said information derived from the various RIS. If there is warning or recall information related to said UPI then the server make **a copy** of said information and then send said information associated with the UPI to the user of the UPI according to the information code associated with said information (B=benficial, H=harmful, R=recall). If not, proceeds to the step at .... If there is warning information related to interaction between the UPI and a biological variable then the server make a copy of said information and then send said information associated with the interaction between UPI and biological variable to the user according to the information code associated with said information (B=benficial, H=harmful, R=recall). If not, it proceeds to the next step at.... Alternatively, the GPI server can electronically couple the user of the UPI product with the site in the internet which contains the warning information, such as the research institution, or the manufacturer, or the FDA, or the CPSC, and the like. The central GPI server then determines whether if there is any warning information associated with a life threatening code, and if there is then autodialing or paging is activated and the user of said UPI informed by phone message of the potential fatal risk at step... otherwise proceeds to the next step. The GPI server then adds the warning information to the e-mail message at step .... and then generate the messages at step..., and then send the messages electronically to the user of said UPI products using the encryption module and according to the warning levels, interactions, and the communications principles of the present invention. As each step is performed the associated data is digitally date-stamped with the time/date module and updated and: added to the product database under the user's IP address if for example a new UPI is acquired, or added to the biological variables database if a new biological variable is acquired, or added to the interaction database if a product-biological variable is acquired, added to the alert database if an unintended effect of a product is acquired, added to the personal information database if a new for instance demographic information is acquired such as a new occupation, and the like. It is understood that alternative embodiments can be implemented with the information sent to the user concerning a warning or recall related to a product being used may also comprising of a web URL, bulletin board address, and the like as well as a voice mail address, phone number, mail address and the like, with all of these contact sources containing relevant information related to said product warning and/or recall.

At this point additional steps can be taken and a variety of health care providers can be engaged based on the information acquired from the RIS and depending on the level of severity of the warning and type of illness/injury. If the warning relates to a harmful product, then it is determined if it is a level 4 medical event, If level of severity is 4 then the EMS is contacted, if not proceed to the next step at.... to determine whether an appointment at a medical institution or doctor is needed at step.... Then if for example a drug as Dexfenfluramine (Redux®) as previously described is used and since the recommendations by the FDA include heart evaluation by a doctor, then the user of the UPI Dexfenfluramine (Redux®) is automatically scheduled for an appointment with a suitable doctor in said user's domicile area. Otherwise it proceed to the next step to determine whether a laboratory test is needed at step... Then if for example a drug as Dexfenfluramine (Redux®) is used and since the recommendations by the FDA include laboratory evaluation with an echocardiogram , then the user of the UPI Dexfenfluramine (Redux®) is automatically scheduled for an echocardiogram in a suitable laboratory or medical institution in said user's domicile area. After the laboratory tests are performed, the results of the laboratory tests are electronically sent to the GPI server and the data is stored in the biological variables database for said user who underwent the laboratory evaluation. Otherwise it proceeds to the next step at...., to determine if a prescription is needed, and if a prescription is needed as recommended by for instance the RIS such as FDA, then the doctor is contacted and prescription sent to a pharmacy in said user's domicile area. Otherwise it proceeds to step ... and determine whether there is need for insurance approval, and then acquire the approval code needed and transfer said code to the various health care providers. Otherwise it proceeds to the next step and generate a record of all of the appointments, and then preferably electronically transfer said appointment information to the user. As each step is performed the associated data can be time-stamped and date-stamped and added to the personal **acquired medical database** under the user's name or IP address. **The** central GPI server has a database containing all the product information previously acquired/received fron the RIS, a list of all user's IP address, a list of all the products (UPI) received, a record of all appointments/tests for each user, a record of the biological variables received, a record of all products-biological variables interaction, a list of the entities providing warning information, and a record of all alert sent to **the users**. MAY REMOVE !

Add new flow with single warning delivered –to be done at Yale

The gpi file server keeps KEEPS a local copy of the product warning information related to the UPI with said product warning information acquired from the RIS, allowing the central gpi server to transfer said UPI warning information to the user as soon as said user send UPI data as using said potentially harmful product. The GPI server creates any number of folders and files for each UPI which is transferred to said GPI server and the selected information from the RIS concerning said UPI is then automatically moved to the folder for said UPI with the IP address of the user of said UPI product being associated with said folder. Whenever new information on a stored product is acquired, the gpi server automatically put it in a folder which is automatically sent to the user of the product. If another user transfer the same UPI code, then the GPI server proceeds with the steps as described and then make a copy of the warning information for the UPI and send said warning information to the new user of product. In an exemplary embodiment the warning information related to the UPI is sent electronically to the user of said UPI product as a message, an attachment or the like. The system can work on information locally stored, but if the information on the unique potentially harmful product sent by the user is not located in the cache of the GPI server, said Gpi server will then connect the user to the remote site in the internet which contains the warning information on said harmful product. If the user is online with the

GPI server, the GPI server will instantaneously transmit all of the warning information, and appointment information if available, to the user, preferably as described in figs (**HTML**) and may connect the user to the remote site in the internet which contains the information on said harmful product. Alternatively the user can e-mail the products identification to the GPI server, which then proceeds to search the stored product information in its database and then later with the user off-line transfer the information to the user according to the various principles described in the invention with said information later retrieved by said user. It is understood that advances in processing and communication medium will allow the unique product identifiers to be automatically and instantaneously uploaded to the GPI server as said unique product identifiers are acquired and/or selected by the user with the subsequent automated processing and transfer of warning information related to said UPIs back to the user of said UPIs.

The GPI system is also designed to acquire information from the user which may be significant from a warning or recall standpoint. In said exemplary embodiment the GPI system uses biological variables to determine if a certain UPI product has been consistently and temporaly broadly associated with an abnormal biological variable. The following illustration will clarify this embodiment. In the case that hundreds of users starting using a certain drug GL with said drug GL UPI associated with these hundreds of users is transferred and stored in the GPI database, and if after staring using said drug GL, these hundreds of user transfer biological variables consistent with abnormal heart rhythm, then said data is transferred to the FDA for instance. In this scenario the GPI system acts as an auxiliary in the detection of harmful products. The same approach applies to the detection of a certain plant number or lot numbers causing widely spread illness or injury, and in this case the GPI system assists the FDA in locating plants for inspection which potentially do not have good manufacturing practice as well as identifying and locating imported products for collection of samples and inspection. It is also understood that data related to a severe life-threatening reaction to any product being used, even if only by one or few individual users, is transmitted to the suitable RIS, for instance if it is a drug causing the life-threatening event, then the data is sent to the FDA computer. CPT!!!!!!!

Another important embodiment and application of the present invention consists of location of the user of food products in a similar manner as previously described. Foodborne illness refers to illness/injury caused by consuming any type of food, and the so called food poisoning ranks second only to the common cold as the most frequent cause of illness in the United States. An amazingly 81 million cases of foodborne illness occurs each year in the United Sates according to the Center for Disease Control with over 6 million of severe cases leading to over 9,000 deaths per year. The single most important step by which these devastating foodborne illness can be controlled is by prevention of spread through the location and warning of the user of the food product, and then with subsequent treatment.

The product identification is uniquely universal number that distinguishes the product or lot of a certain product from any other products allowing thus all of the products from that "contaminated" lot to identified with a warning sent to the user regardless of the location of the product. Let's consider food product such as canned beans products manufactured in a plant # 3 by employees in Section D in New York from January 10 to 15th, 1998. These products were distributed across the US and the world. It was later found out that contamination of products occurred during processing in that particular plant,section, and dates. In this case although the contaminated product has been distributed across the country, the few users of that particular lot # are alerted in the same individual and confidential fashion with precise location of the user with minimal cost for the manufacturer that only have to send the alert to the few consumers who bought the product which was processed by that vey particular plant, section and dates. The

coding system can include identification numbers for the entire food distribution chain including producers, packers and shippers, processors and manufacturers, and retailers allowing the system to precisely pin point who are the consumers of the potentially harmful food or drink product without having to rely on public announcement as it is conventionally done. Furthermore, the users of the product can transmit information to the GPI system about their symptoms and comments on the product such as labeling, appearance, questionable ingredients, and the like. When a certain number of users report similar symptoms after ingesting the same food, eg, food with the same identification code, the GPI system identifies a potential outbreak caused by a products which share the same characteristics, eg, the same code or partial code, the identification code. The system then can transfer this information back to the RIS, in this case likely the FDA and the CDC. Another embodiment includes identification of potential allergens disclosed in the label or undisclosed.

FOOD- particular pesticide/commodity combinations by analyzing certain foods to determine the presence and levels of selected pesticides

A foodborne disease outbreak is defined as a group of people developing the same illnesses after ingesting the same food.
the spectrum offoodborne disease is changing. New infections not previously known to be foodborne diseases are emerging. Approximately 400-500 foodborne disease outbreaks are reported each year.
Government officials and health experts consistently rate foodborne illnesses as the greatest food safety threat. Their effects can range from relatively minor discomfort to more serious symptoms and manifestations such as fever, diarrhea, vomiting, dehydration and even death. The acute illnesses posed by foodborne organisms, coupled with the ease and swiftness difficulties in locating the user with which they develop, present food safety challenges

emerging risks need to be monitored for several reasons. First, the food supply of the United States is changing dramatically, The conditions under which food animals are raised have changed greatly. We now import 30 billion tons of food a year, including fruit, vegetables, seafoods, and canned goods; these imported foods are an increasing proportion of the diet, and often come from developing countries where food hygiene and basic sanitation is less advanced. Food processing technologies are constantly evolving. The centralization of the food industry means that a single contaminated product may appear in many different foods and many different forms, and infect a considerable number of people before it is identified. Ad once identified the source there are nomeans to effectively alert the user of the contaminated food. Finally, new and emerging foodborne pathogens have been identified, which can cause diseases unrecognized 50 years ago. These include bacteria, parasites, and viruses, along with toxic causes of foodborne illnesses. Constant vigilance is necessary to identify new problems requiring new solutions as they emerge.

Another source of foodborne infections is shellfish contaminated with toxins.Some of the toxins or poisons that contaminate the shellfish are paralyticshellfish poison, neurologic shellfish poison, diarrheic shellfish poison,and amnesic shellfish poison. These neurotoxins are among the most potent toxins known.They can interfere with sensory, cerebellar, and motor functions. Symptomsusually occur within 30 minutes and high doses can lead to diaphragmaticparalysis, respiratory failure and death. Thereare no laboratory test to detect toxin within an individual. There are noanti-toxins or antidotes available for treatment of shellfish poisoning, andno other chemotherapy has proven effective. Therefore, treatment issupportive care of infected person.

A person with listeriosis usually has fever, muscle aches, and sometimes gastrointestinal symptoms such as nausea or diarrhea. If infection spreads to the nervous system, symptoms such as headache, stiff neck, confusion, loss of balance, or convulsions can occur.

LOGIC FOR SERVER Fig -- *showswhen the c. establishes connection, the – returns a messge indicating--. Call with arequest tosend the messge addressed to the server The user application send* The GPI server may request for instance information from the various RIS related to a selected product storage in the GPI memory, or alternatively the various RIS automatically transfer information on recalled products to the GPI server as soon as the information is available, according to standard techniques and encrypted transfering of information. In an exemplary embodiment, at step--- the GPI server receives/acquires product recall information (eg, recall information associated with a product identifier, such as UPI or alternatively the name of the product) from the RIS. **The server then store the code for the product and information for said product in the RIS database at step---. Search applications are then** engaged to check the product databases at step.... to determine if there is any username associated with the transmitted UPI or product identifier. The GPI server searches the product database for all of the users associated with the UPI. If there is any username associated with said transmitted product identifier, then said associated username with IP address is selected, otherwise the UPI information acquired/received from the RIS is stored in the alert database in the recall memory area#. The central GPI server then determines whether if there is any warning information associated with a life threatening code, and if there is then autodialing or paging is activated and the user of said UPI informed by phone message of the potential fatal risk at step... using the phone number stored in the personal information database, otherwise proceeds to the next step. At step--- a message with the recall information and product identifier is generated, and then at step --- said message/information is transmitted to all users of said UPI according to the corresponding username/IP address.

Although the system is designed to be a completely free service, for the purpose of completion of description, it is understood that the system may prompt the user for a credit card number for example before any data can be transferred to the main GPI server.
NEED TO BE INCLUDED SOMEWHERE also ACCOUNT DATABASE11!

As mentioned, the present invention corrects all of the problems with the prior art
Canned foods
Various warning stages

LOGIC-RETRIEVING accoridng ot products stored In an exemplary embodiment the GPI server receives updates on product recall and warnings regardless if the product name or code is present in the GPI database , for instance the GPI server receives a warning from the manufacturer of drug Z or the FDA and said data on product Z with unique identifier 1212100012 is stored in the RIS database in the warning memory area.... with said data being checked against the GPI product database, and if users of drug Z are found, then the warning data for product is sent to the users according to the principles of the invention, if no users of drug Z are found in the database then the warning data for drug Z is stored in the Alert database, and when an user transfer data related to using drug Z, the warning information is copied and sent to the user of drug Z. In another exemplary embodiment of the invention, the central GPI server searches for information according to the names or identifiers of the products stored in the GPI database and then searches the Domain name of the RIS sites where the resource is located, the directory path to the resource, the name of the file, ports, and so on, preferably using resource addressing as standard Uniform Resource Locators concerning information sources related to the products names and/or

codes stored in the GPI product database allowing the precise searching of databases and access to the needed files with the binary file related to the code/name products in the product database sent to the user. In another illustration if a product P is stored in the GPI product database, then the files related to product P available for instance in a FTP site are retrieved, stored in the RIS database and then sent to the users of product P. If there are messages and attachments related to the product then the GPI server using conventional software automatically encode said attachment to send it across the internet. Fig 111 shows an exemplary embodiment in which the GPI server establishes on-line connection with the RIS at step---. The GPI server then access the RIS database at step --. The GPI server then searches the RIS database at step-- for information related to the stored UPIs in the product database or any Beneficial, Harmful, or Recall information for any UPI. The GPI server then retrieves and transfer the information acquired from the RIS at step---, and then stores said information in the RIS database at step--. The GPI server then searches for all usernames in the product database which are associated with the acquired UPI at step--, and then generates a message with the UPI information to said usernames. The GPI server then preferably electronically transmits a message and information on the products (UPI) to all of the users of said products.

In an alternative embodiment, the GPI server generates a product key according to the product stored in the product database. This key may be the UPI itself or a newly created key. The GPI server then transmit said key to all of the users of the product. The user then receives the key and stores the key. The key is necessary to enter a room for example an electronic room, board or window found on commercial on-line providers as AOL. The user then uses the key to access the room, and to retrieve the data. A variety of rooms can be created according to UPI and/or biological variables and/or medical conditions associated with a number of users. Moreover, for instance the users of the same recalled product who sustained harm caused by the product can communicate with each other creating thus a support system for the victims allowing said victims to share experiences, tips on treatment, how to personally control certain symptoms, and the like. If the user deletes a UPI, biological variable or medical condition in said user database, then the GPI server determine whether the user is qualified to enter a specific room and then may void the key. As previously stated, the GPI arrangement is designed to be a completely free system to any user of any product, but for the sake of completion of description few exemplary compensation methods are described. Naturally the receipt of the above key may only occur after the occurrence of appropriate transfer of funds to the GPI server and/or to a third party. Furthermore, appropriate transfer of funds to the GPI server and/or a third party may be required at any time and may occur at any of the steps described in this whole specification. It is also understood that tracking arrangement for the number of requests and/or information delivered or acquired by either the user or/and the RIS can be used as means to quantify and charge for the use of the system. There are herein described only few embodiments and modifications concerning environment as well as compensation issues, but it is understood that the invention is capable of use in various other environments in conventional messaging and broadcasting, and any other combinations, as well as in any 'cyberspace" environment based on the internet and using a variety of payment methods.

Referring now to figure 1, there is depicted the simplified system necessary to carry out the present invention which includes a user, a input device for manual entry such as a personal computer, communications interface, a central server, the RIS and HCP. Still referring to fig.1—a computer system consisting of an exemplary embodiment for a user interface may consist of a typical personal computer having input means such as keyboard, microphone, mouse, and the like, processing means, display means, and network interface. Fig 1A shows an exemplary user interface consisting of a CPU, ROM, RAM, input device, memory device, video driver, video monitor, clock and modem. It is understood that the hand-held computer such as the described

PDA can have similar architecture as the computer system depicted in fig 1and 1A.
Fig—shows an even more simplified system to carry out the invention which includes a user, a input device for manual entry such as a personal digital assistant or a conventional touch-screen device, communications interface, a central server, and the RIS

Avoid wasting time, wasting money, overload, tremendous burden on the internet
e-mail from automated program

Another embodiment relates to the timely intervention and appointments scheduling according to the transmission of biological data which is shown in fig.---. Patients sometimes come to their doctor at a too late stage in which sometimes irreversible damage or life-threatening complications have already occurred. It is very difficult to evaluate with certainty when an appointment is needed for a certain patient or certain condition. Sometimes if the patient had came just a few days earlier, a life could have been saved or irreversible and costly complications prevented. For instance patients with renal failure or heart failure need a very strict control of their body weight to avoid potentially fatal complications such as decompensation of heart failure and/or pulmonary edema. Patients may call the doctor's office for an appointment, but most of the time if they do not have any clearly warning symptoms, the appointment is scheduled according to the openings in the doctor's schedule which most of the time is too late and severe complications have already occurred. With the GPI system those patients have for instance a scale or any other medical monitoring device with an IR or RF emitter which interfaces with the IELCD, and the IECLD interfaces with a computer system. The binary data is then subsequently transmitted over the internet to the biological variables database at step ---, with said data being time and date-stamped using the time-date module at step---. The data is then transmitted to the insurance company or Medicare provider at step -- for said patient if approved by the patient according to information stored in the personal information database. The data is then stored in the biological variables database at step---. The values stored are checked to determine whether those are normal values for said patient at step---. If there are abnormal values then a message is generated at step-- and sent to patient at step---. The IECLD continuously feed the information about the patient's weight to the biological variables database in which the patient's record is stored with said information evaluated against the range of values stored on the normal values database to determine if said values are considered safe for said patient. The timestamp allows the GPI server to decide if said patient is compliant with his health monitoring. If the biological variables database receives monitoring of the weight punctually at step---, then a message is sent informing the patient. Otherwise proceeds to the next step at---, and the range of values received is checked against the drug database and medical history field to determine whether said range of values put the patient at risk for an acute event. For instance if a patient is using a drug for heart disease stored in the drug database and said patient has gained 5 pounds within a certain period, this can indicate heart failure, the same would apply if said patient transmit blood gases as per devices by Abreu indicating respiratory insufficiency also indicating risk for an acute medical event, and most importantly before any symptoms appear which would alert said patient to seek medical attention. If the patient is then at risk of acute event, then an insurance approval is acquired at step-- and automatic appointment scheduled at step---. A message then is generated with the above information at step—and sent both to the patient at step-- and to his medical provider at step----. This would allow patients to be continuously monitored and timely intervention provided according to objective values of biological variables. When patients gain excessive weight and arrived at the doctor's office with heart failure and/or pulmonary edema or at the risk of pulmonary edema, said patients usually would have to be admitted to a hospital incurring a lengthy and costly admission. Any biological variable or condition could be monitored and this fashion providing life-saving interventions while substantially diminishing health care expenditure by avoiding preventable complications with the consequent saving of the

financial resources for the government, private companies, and ultimately the public in general.

WebTV communicates the signal to the TV

Although the preferred embodiment concerns the electronic transfer of information, the invention can be carried out using conventional communication means as previously mentioned. In those alternative illustrative embodiments, the user can utilize conventional telephone line to communicate with the GPI serve which can direct the user to a human attendant which register the user and collects the personal information, UPI data and biological variables data if applicable, and then said attendant converts the data into binary elements and transmits and stores the data in the GPI server in the manner previously described, or alternatively a digitized faxed information could be acquired and processed in a similar manner. Once the user is registered the whole entering of data can be done automatically without human interference since the data consists of numbers for either the UPIs or the biological variables which can be done using the telephone keypad and conventional Interactive Voice Response Unit. The user can then contact the GPI server to receive feedback information on the products being used with said GPI server converting text into audio with standard electronic voice synthesizers. Although less preferable, it is intended that the current invention can also be carried out using printed medium which is converted into binary elements and used in accordance with the principles of the invention previously described.

In yet another exemplary embodiment as well as description the user carries a modified IECLD which consists of the hand-held self-monitor detector by Abreu in which there is either a detachable conventional IECLD or preferably a built-in IECLD with bar code reading capabilities and other features as previously described. The user, Mr. Martin, is on a 3 months working trip in Switzerland. The user is then at the train station, and while waiting for the train the user checks his eye pressure, blood cholesterol and blood sugar using the aforementioned Abreu self-monitoring devices with the biological variables (eye pressure, blood cholesterol and blood sugar) being wirelessly transmitted via the internet to the GPI server remotely located for example in the US. As soon as said biological variables are received by the GPI server, the blood sugar and cholesterol values are found to be acceptable, however, the eye pressure value is found to be abnormally high for said user, and considering that the user is using amiodarone, stored in the drug database, with said amiodarone potentially causing optic nerve damage, then the GPI server identifies the harmful interaction causing eye damage, and then generate a harmful alert with instructions. The GPI server also searches and identifies a newly recalled product (for instance the drug appetite suppressant Redux®) which is stored in this Mr. Martin's list of drugs stored in the drug database. The GPI also identifies a newly recalled chocolate which was found to have undisclosed amounts of peanuts, and since the user is alergic to peanuts a critical alert is generated. The GPI also had identified a recalled crib being used by Mr. Martin's son and informs the user that a successful phone alert was sent and received, and entered as Mrs. Martin as the recipient of the phone call alert. Since it has been more than 3 weeks since Mr. Martin transferred his weight data, the system send a remainder about checking weight. All of this information is then automatically transmitted back to the user via the internet, and if the user has a doctor's name in Switzerland stored in his personal information database then a doctor's appointment is also scheduled. The warning information and instructions is then wirelessly transmitted to the hand-held modified IECLD with audible and visual means informing the user that an important message was sent. The user then retrieves the message and checks the warning information which have helped him not to go blind by detecting the harmful product-biological variable combination, have helped him not to develop a serious and disabling heart disease by identifying a recalled drug, have helped him not to develop a potentially fatal alergic reaction by identifying a recalled chocolate contaminated with peanuts, reminded him about checking his

weight and informed him that although his son was at risk of serious harm and death by using a recalled crib, a phone alert was sent and received by his wife back in the US as well as helping him to save time, effort and money by scheduling the appointment with his insurance approved and personally known doctor in Switzerland. The user then thinks, this is great, I just wish I could have stored in the GPI site the train schedule in Switzerland and my credit card number, so I would know what train to take to get to my doctor and would have an already purchased ticket for the trip, and then adds "Oh! 10 minutes already went by, my train has arrived!"

The foregoing description of the preferred embodiments of the present invention have been provided for the purposes of illustration and description. Obviously many modifications and variations will be apparent to those skilled in the art. The embodiments were chosen in order not to limit the scope of the invention but to best explain the principles of the invention and its practical applications.

_----------end of summary to be submitted

Another embodiment of the present invention relates to the transmission of biological data acquired using diagnostic or monitoring tests as described in the Patents by Abreu or any diagnostic or monitoring device. The DMC would be a hand-held device which would interface with the various monitoring and diagnostic devices via a low power RF or IR interface. The DMC could be activated at prescribed intervals to store the biological data which was received from the other monitoring devices and to subsequently deliver the biological data over a public network such as the Internet and to a server and then to a database. It is also understood that the DMC could be placed next to the monitoring device in order to receive the biological data at the time of measuring said biological data. The data could then be stored for later transmission or the data could be immediately transmitted over the public network to the corresponding database. In either case the biological data Z such as blood glucose level or data E such as eye pressure would be transmitted to the corresponding biological database and then routed to the Z and E domains respectively. According to the level measured of the biological data, a feedback information would be sent automatically to the user. In case the random evaluation of eye pressure shows a value which potentially put that user at risk for glaucoma, the user would receive information about the disease and how to proceed. If the level of the variable could create a health hazard it would also carry a warning message. The user of the DMC could also interrogate the database for the various biological variables being tested. For instance a user who has glaucoma or is that the risk for glaucoma would be able to interrogate the glaucoma domain regardless of the level of the pressure. However if the eye pressure would be creating a health hazard the patient would be automaticaly informed about such hazard and how to proceed. An appropriate alert would also be sent to the patient's medical provider and pharmacy provider. The same information will also be sent to the insurance company with a request for authorization of a medical appointment based on the results of the objective test such as dangerously increased eye pressure. According to the level of said biological data and the health hazard a medical appointment with the appropriate doctor or specialist would be generated by the insurance company. The name of one or more medical providers, dates, and locations as well as an authorization number would be sent back to the patient's DMC which then would allow the patient to choose the provider and dates that best fit his condition. This system could prove to save lives and costs by providing objective values that could be easily compared to what is considered the safe range of values for said user, instead of using uncertain and inconsistent symptoms and complaints by the user which are very difficult to be analyzed and evaluated. Any objective biological variable could be transmitted by the user with the appropriate feedback and information sent to the user's DMC according to the level of said biological variable.

Another embodiment relates to the detection of drug interaction with certain levels of biological

variables. The DMC stores all of the pharmaco-active compounds, implanted materials inside the body or externally placed, treatment received such as chemotherapy, surgical procedures and the like. Whenever the user monitors biological variables, the range of such biological variables is evaluated against the various elements stored in the DMC or in the database correspondent to the user. For instance if the user monitors a variety of biological variables and one of them dangerously interact with the elements stored in the DMC or the database, the user would be alerted in regards to that. For instance if a non-hypertensive patient is using Sildenafil and measured his blood pressure routinely and the biological variable (blood pressure) is found to be at the levels that could interact with the drug, the user would be alerted for that fact. Any element that interact with drugs including nutritional products could be a stored in the DMC or database and evaluated against said biological variable. For instance data such as certain wine and cheese containing tyramine could be stored in the DMC's memory or the database and if a medical provider or the patient would enter drugs such as mono-amino oxidase inhibitors, this data would be sent to the respective hypertension domain and a warning about this fatal interaction between certain cheese/wine and the drug would be displayed on a user's computer screen or TV screen or e-mail or directly into the DMC screen or through conventional phone connection with an auto-dialing feature. Although less reliable, the patient also could enter symptoms using an already loaded questionnaire into the DMC with said symptoms being evaluated against the other biological variables for the presence of any health hazard.

Invention relies on objective data such as bv and products, and not symptoms described by pt

Abreu has described in his patent a system in which no numerical values are displayed in the display in relation to providing output related to measured biological variables. Abreu utilizes a system of lights which corresponds to the range of values for the biological variables. The DMC provides an improvement over Abreu's invention by providing an interactive display in which the user would receive information and information on how to proceed according to the level of the biological variable measured. For instance when measuring ocular pressure if the pressure is within acceptable levels, the green light by Abreu would appear. In the present invention a message would appear stating that "You are fine" and "You should keep the appointment with Dr. Jones at 6 p.m. on January 1st. Please bring your glasses and medications with you". Since there was a record entered by the doctor that the patient did not bring his glasses with him in the previous appointment, the DMC will remind the patient of that. A list of the medications with its schedule would subsequently appear on the screen indicating which should be the next medications to be taken and what is the dosage to be taken. The patient could then interrogate the DMC in regards to the meaning of the level of the pressure measured and then receive information stored in the DMC's memory in regards to what that level of pressure means for that particular patient according to the patient's specific health status. If the pressure measured was within borderline values, the yellow light by Abreu would appear. In the present invention, a message would appear stating " Your eye pressure is borderline and you should check your eye pressure again in three hours. If you experience any eye pain please press the contact office button on your screen." If the eye pressure measured is above acceptable levels, the red light by Abreu would appear. In the present invention, a message would appear stating " Your eye pressure is above acceptable limits. Please check your eye pressure again in 15 minutes. If you experience any eye pain or redness please press the contact office button on your screen." If the pressure measured is very high which could potentially cause reversible damage in a short period of time, the present invention would display a message stating "Please come to the office for evaluation. Your pressure is well above acceptable safe limits." A warning message about the patient's condition would also be transmitted to the medical provider's office over the public network. Please note that each DMC would be calibrated according to the range of pressure which is considered safe for that particular patient and according to the overall health status of

that patient. It is also understood that the above disclosed technology could be applied to any other home monitoring device such as blood sugar monitoring as described by Abreu, blood pressure measuring devices, heart monitors, pregnancy tests and the like.

For instance, some pharmacological compounds are approved for public use and are later found to be contraindicated in the presence of certain diseases or caused fatal reactions and complications. A couple of examples will illustrate the use of the invention. A drug to treat allergies widely advertised on TV by the name Loratadine, as previously mentioned (pharmacological name) was found to cause esophagus rupture with even potential fatal complications due to the size of the tablet. Although some Doctors are notified by regular mail, patients have no means to know the new complication caused by the drug unless informed by their doctors or in rare occasions through the media. Even after the announcement to doctors of those devastating complications, patients still perished due the lack of knowledge of such severe complications because some times is difficult for the doctor to inform their patients since patients come to the office in a random basis. Furthermore, it is an unsourmountable task to physically review all of the charts, identify every patient using drug X., and then to call or send correspondence warning said patients about the new complication or reaction which was found with the drug X. that they are using. Recently, a drug used to treat by the name Sildenafil used to treat erectile disfunction was found to have potential fatal reactions when used by patients with certain cardiovascular disorders which was detected after widespread utilization of the drug.

The present invention allow a totally automated system of acquiring, processing, transmitting, and receiving information without the need for human interference for a response to be delivered. In accordance with the present invention the process of acquisition of the biological data or factors which alter biological data involves preferably the use of a portable hand-held unit called the electronic communicator and locator (IECLD) which is used for both input and output of data as well as to interface with the various monitoring devices, the public network, computer screens and television screens, and the like. The IECLD will also store in its memory all of the information concerning the health status of the user including blood tests which were performed, results of imaging studies such as X-rays, CTs and MRIs, treatment received and drugs being used, surgical operations undertaken, implants placed internally or externally, substances placed on the surface of the body or ingested, and the like. The IECLD can then transmit the stored information as electronic data over a public network such as the Internet with said data being transmitted to a General Product Information (GPI) Server for storage and processing in order for feedback information to be retrieved and the delivered to the DMC user. When the DMC uploads data which contains code for requesting information from the GPI, the DMC browser automatically will issue a command for the retrieval of information regarding the biological variables which were uploaded.

Although anyways to connect to the Internet can be used as described, a preferred way primarily for elderly patients monitoring their health would be by using a television connection since a television set is much more familiar to some elderly patients than computer screens. On such approach uses a set-top box that connects the TV to the Internet via a modem taking the information from the GPI server and delivering it to the TV screen or simply using cable modems that offer high-speed access to the GPI server. In this particular embodiment the DMC hand-held device may serve as a remote control like device that allows information from the Medical Monitor Database to be displayed on the TV screen while simultaneously watching TV programs. And In another embodiment the DMC uses network computers in which all of the biological data and personal user information are stored in the Internet in the special secure network computer

servers utilizing for example Java based software. Page 85 No. 6 in an another embodiment whenever the FDA server sends a warning sign to the GPI server related to drug X, an automatic email message " warning" will be sent to the DMC user who uses drug X as well as a fully formatted Web page with a link to the drug X domain in the GPI server.

Since preferably the DMC is portable, patients can carry the device to their medical appointment allowing the medical provider to enter whatever data that is relevant to that patient, from changing the dosage or the type of the medications to adding a new surgical procedure that was performed or a new skin cream that has been prescribed with this new data being stored in the DMC memory and available for further transmission to the GPI server as well as to other sites which will be described in detail later. Besides inputting data using the portable personal DMC, a less desirable and actually inefficient way would be for the doctor to enter the data using a computer keyboard, but to do that each room must have a computer in each room that the doctor sees patients and the doctor would have to enter a patient's code and then to access the GPI server, and then make corrections and input the new information. For every patient the doctor would have to individually enter their particular code and perform this time consuming operation, which is virtually impractical.. With the DMC the time consuming operation of entering and downloading data can be comfortably done by the patient at home. The doctor or doctor's assistant only would have to enter the new data into the DMC or would instruct the patient to enter his/her own new data with the patient downloading the new data stored in the DMC at a later time. The DMC can be interfaced with a printer in the doctor's office and any changes made in the drug regimen would be available as a prescription slip for the new regimen and given to the patient.

In accordance to that, systems in which subjective symptoms are used or systems in which there is a need for human interference or a human operator are dependent on many unreliable variables, skill and knowledge of the operator, subjective interpretation, and increased costs of operation of the system. Interpretation by human observers of subjective symptoms and complaints are subject to errors and multiple different responses according to each individual interpretation and are thus far from ideal. Systems in which the user has to enter subjective data or symptoms or systems in which the user has to respond to instructions provided by a human operator requires the continuos entering of subjective data by the user and the continuous presence of skilled operator.

The user can type in the GPI domain and the access code, or preferably the domain is contacted directly by the DMC browser anytime a biological variable is uploaded by the DMC user. The browser in the DMC or a computer browser conected to the DMC or a television set connected to the DMC through a communications program contact the server which contains the medical monitor database GPI, If a modem is used, a communication program dials the modem allowing the DMC browser to send a request to the GPI server using Internet Protocol or Transmission Control Protocol. The biological data stored in the DMC user is then delivered to the server GPI, and if the data concerns drug X, said data is then delivered to subdomain drug X or a specific computer which has information on drug X. The DMC browser requests a specific Web page from the GPI server concerning drug X.
If for instance the DMC user upload data related to to a particular orthopedic prosthesis which has been surgically implanted, and connect to the Internet, the GPI Web server analyzes the data and may send an article related to the precautions and issues newly found about said prosthesis. If for instance the DMC user upload data related to a special contact lens such as the intelligent contact lens described by Abreu, a video file with information on how to hold to and manipulate the lens is automatically sent to the DMC user which has intelligent contact l the ens stored in its memory.

Important note-there may be some software which will enable communication directly from the DML user to the M. M. D. database without having to go through a server

Software turn us your voice into binary data files that computers can read

116 just as you need a browser to use the Web, you need a special user software, what the generically call Internet tools, to get at others parts of the Internet

HH If the user exceeds the limit determined by the criteria , a warning message will appear or an automated dialing system is activated, and a new target for weight would be set up

because older patients often need to take multiple medications and metabolize drugs differently than younger patients, seniors run a much greater risk of medical complications and even hospitalization due to adverse reactions to their drugs.
. The idea was to provide patients and physicians with information about best medical practices and recognized prescribing guidelines in order to reduce the risk of harm from inappropriate prescriptions.
A study published this year by a group of Merck-Medco clinicians and researchers in the Journal of the American Medical Association shows that our efforts are paying off. When our pharmacists counseled physicians about prescriptions that might harm their patients, the study showed that the *Partners for Healthy Aging* program generated changes to safer prescriptions at a rate that was 12 times greater than occurs in the usual practice of pharmacy without such structured programs.
Partners for Healthy Aging, like our *Optimal Outcomes* health management programs, is based on the principle that careful attention to all aspects of care for patients who are at the greatest risk can produce measurable improvements in health, quality of life and overall costs.

Actions to prevent the occurrence and avoid the spread of disease due to lack of idebtification and location of the harmful product or contaminated individual is critical fo rthe cointainment of the acceleration in health care spending

. companies will encourage the use of the DMC, which can be doen efficintly and in a private manner, in order to avoid bad publicity when recalls are done through the media as it is the conventional way of recalling defective products currently used.

Need food/cosmetics

The hazard of inadequately preserved cosmetics to human health has been amply demonstrated by reports of staphylococcal infections in hospitals from use of contaminated hand creams and hand lotions and in studies conducted on eye area cosmetics. Contaminated cosmetics for the eye area, such as mascara contaminated with Pseudomonas aeruginosa may lead to partial or total blindness associated with devastating symptoms such as intractable pain and continuous tearing and light sensitivity. Virtualy disabling a person during the disease state. Many cases of corneal ulceration and blindness associated with Pseudomonas-contaminated mascaras have been identified.

use levels of certain selected ingredients which have been found to cause depigmentation, irritant, neurotoxic, or phototoxic or other allergic reactions.

Investigation plant ispections shows that not current good manufacturing practice then recall, DMC will alert. FDA collects cosmetic product samples as part of its plant inspections, import inspections,

If new benefitial data ir useful data appears later on the DMC

(they've been widely available only since a bout 1992) means that their long-term effects are unknown. An industry-sponsored study found that people who use AHA products have greater sensitivity to sun, raising the specter of greater risk of photoaging and skin cancer. cosmetics containing alpha hydroxy acids (AHAs). AHAs attract customers with their supposed ability to reduce wrinkles, spots, and other signs of aging.

identifiable product code numbers

Recalls are voluntary actions taken by the cosmetic industry to call back products that present a hazard or that are somehow defective. product may be injurious to users product is harmful under conditions of use The Cosmetic Adverse Reaction Monitoring Database of the Office of Cosmetics and Colors (OCAC). is comprised of consumer adverse reaction reports received at the Food and Drug Administration (FDA) Headquarters, FDA District Offices, and FDA MedWatch Program.
The OCAC estimates that it may receive only a small percentage of cosmetic complaints reported by consumers. Complaints may be more frequently filed with with poison control centers, state and local agencies, or with the product manufacturer and/or distributor who are not required to submit their complaint files to FDA.
Although NSAIDs are effective in relieving pain and inflammation, they can cause serious gastrointestinal (GI) side effects, including ulcers of the GI tract, bleeding and stomach perforations. In the United States alone, more than 107,000 hospitalizations and 16,500 deaths each year are attributed to NSAID use.

!!! ALSO CASIOConsumers can check the listing to identify substances they wish to avoid. And becoming familiar with what cosmetics contain can help counter some of the alluring appeal showcased elsewhere on the product.

"Our best friend is the ingredient label," says beauty consultant Paula Begoun. "And spending the time to read it may be all that is needed to protect ourselves from hurting our skin."
But the ingredient list, although a mandatory requirement on cosmetics, is also the most difficult part of the label to understand. Bailey admits that most of us don't recognize the names of the ingredients listed because there are thousands available to chemists creating a wide variety of products. But there's no way to change that, he says, and still accurately identify the substances that are used. !!!

check the listing to identify substances they wish to avoid
MANY ingredients, because of the dangers they impose, are either restricted or prohibited

Color additives have long been a part of human culture. approved substances may be used to color foods, drugs, cosmetics, and medical devices. In the late 1800s, some manufacturers colored products with potentially poisonous mineral- and metal-based compounds. Toxic chemicals tinted certain candies and pickles, while other color additives contained arsenic or similar poisons. Historical records show that injuries, even deaths, resulted from tainted colorants. Food producers also deceived customers by employing color additives to mask poor product quality or spoiled stock.

By the turn of the century, unmonitored color additives had spread through the marketplace in all sorts of popular foods, It was not until passage of the Federal Food, Drug, and Cosmetic Act of 1938 that FDA's mandate included the full range of color designations consumers still can read on product packages: "FD&C" (permitted in food, drugs and cosmetic); "D&C" (for use in drugs and cosmetics) and "Ext. D&C" (colors for external-use drug and cosmetics).

One incident in the 1950s, in which scores of children contracted diarrhea from Halloween candy and popcorn colored with large amounts of FD&C Orange No. 1, led FDA to retest food colors. As a result, in 1960, the 1938 law was amended to broaden FDA's scope and allow the agency to set limits on how much color could be safely added to products.

FDA also instituted a pre-marketing approval process, which requires color producers to ensure, before marketing, that products are safe and properly labeled. Should safety questions arise later, colors can be reexamined. The 1960 measures put color additives already on the market into a "provisional" listing. This allowed continued use of the colors pending FDA's conclusions on safety.

With this rainbow hodgepodge bombarding us daily, it's only natural that consumers might wonder: Just how safe are all these colors?

FDA ensures that colors on the market are safe for their intended purposes and do not cover up product inferiority or otherwise deceive consumers. foods, over-the-counter and prescription drugs, cosmetics, or in medical devices such as surgical sutures and contact lenses.

color contains no cancer-causing substances

FD&C Red No. 3color causes thyroid tumors in male rats For now, Red No. 3 can be used in foods and oral medications. Products such as maraschino cherries, bubble gum, baked goods, and all sorts of snack foods and candy may contain Red No. 3. At the same time, Red No. 3 has "permanent" listings for food and drug uses that are still allowed although the agency has announced plans to propose revoking these uses as well.

If Red No. 3 joins the ranks of colors forbidden for all uses, it won't be the first FD&C Red in recent years to be pulled from the market. WHEN THIS HAPPENS dmC WILL Alert THE USER

FD&C Red No. 2 at a high dosage results in a statistically significant increase" in malignant tumors in female rats. FDA ultimately decided to ban the color because it had not been shown to be safe. The agency based its decision in part on the presumption that the color might cause cancer.

- Technology is moving toward a time when chemical substances could be evaluated accurately with a battery of short-term tests conducted in the test tube. Such analyses would greatly shorten the time and expense of evaluating not only colors but other food additives and environmental chemicals

The testing that helps to establish the safety of products, such as drugs and medical devices, is typically conducted on small groups before FDA approves the products for sale. Some problems can remain unknown, only to be discovered when a product is used by a large number of people.

- FDA also welcomes reports through MedWatch of product quality problems. For example, you can report product contamination (suspicious foul odors or unusual "off"

colors); defective –is coded-- components; labeling concerns (such as mix-ups due to similar names or packaging); or questionable product stability.

Worseing of the problem In the last 20 years, the volume of imported goods the agency regulates has tripled from an estimated half million shipments in 1971 to about one and a half million today. To meet the rising demands on the agency of the burgeoning import trade, FDA has increased its import operations

for receiving clear and more timely information about our products

JA USEI!!!! FOOD- particular pesticide/commodity combinations by analyzing certain foods to determine the presence and levels of selected pesticides
The latter focused on domestic and imported fresh apples and processed rice. This is the second FDA survey of this type; the first covered domestic and imported pears and tomatoes, (as well as radionuclides, industrial chemicals, toxic elements, trace and macro elements, vitamin B6, and folic acid)

Foodborne illness generally refers to illnesses caused by microorganisms consumed by eating any type of food. Foodborne illness so called food poisoning ranks second only to the common cold as the most frequent cause of illness in this country with 81 million cases of foodborne illness occurring each year according to the Center for Disease Control. In 1983, it was estimated that there were approximately 6 million cases ofinfectious foodborne diseases which caused 9,000 deaths. Outbreaks of illness from food contaminated by harmful bacteria are especially common. most of these hazards can be controlled by locatio ad prevetion of spread, treatment. More than 250 different diseases have been described that can be caused bycontaminated food or drink. The most common foodborne diseases are infectionscaused by bacteria, such as Salmonella and Campylobacter, or by the Norwalkfamily of viruses. A foodborne disease outbreak is defined as a group of people developing the same illnesses after ingesting the same food.
the spectrum offoodborne disease is changing. New infections not previously known to befoodborne diseases are emerging.Approximately 400-500 foodborne disease outbreaks are reported each year.
single most important step in preventing foodborne disease.Preventing spread of contamination from raw foods in the kitchen is alsoimportant
Government officials and health experts consistently rate foodborne illnesses as the greatest food safety threat. Their effects can range from relatively minor discomfort to more serious symptoms and manifestations such as fever, diarrhea, vomiting, dehydration and even death. The acute illnesses posed by foodborne organisms, coupled with the ease and swiftness difficulties in locating the user with which they develop, present food safety challenges for the entire food distribution chain. This includes producers, packers and shippers, processors and manufacturers, retailers and consumers.

emerging risks need to be monitored for several reasons. First, the food supply of the United States is changing dramatically, The conditions under which food animals are raised have changed greatly. We now import 30 billion tons of food a year, including fruit, vegetables, seafoods, and canned goods; these imported foods are an increasing proportion of the diet, and often come from developing countries where food hygiene and basic sanitation is less advanced. Food processing technologies are constantly evolving. The centralization of the food industry means that a single contaminated product may appear in many different foods and many different forms, and infect a considerable number of people before it is identified. Ad once identified the source there are nomeans to effectively alert the user of the contaminated food. Finally, new and emerging foodborne pathogens have been identified, which can cause

diseases unrecognized 50 years ago. These include bacteria, parasites, and viruses, along with toxic causes of foodborne illnesses. Constant vigilance is necessary to identify new problems requiring new solutions as they emerge.

Another source of foodborne infections is shellfish contaminated with toxins.Some of the toxins or poisons that contaminate the shellfish are paralyticshellfish poison, neurologic shellfish poison, diarrheic shellfish poison,and amnesic shellfish poison. These neurotoxins are among the most potent toxins known.They can interfere with sensory, cerebellar, and motor functions. Symptomsusually occur within 30 minutes and high doses can lead to diaphragmaticparalysis, respiratory failure and death. Thereare no laboratory test to detect toxin within an individual. There are noanti-toxins or antidotes available for treatment of shellfish poisoning, andno other chemotherapy has proven effective. Therefore, treatment issupportive care of infected person.

A person with listeriosis usually has fever, muscle aches, and sometimes gastrointestinal symptoms such as nausea or diarrhea. If infection spreads to the nervous system, symptoms such as headache, stiff neck, confusion, loss of balance, or convulsions can occur.

Infected pregnant women may experience only a mild, flu-like illness; however, infection during pregnancy can lead to premature delivery, infection of the newborn, or even stillbirth. When infection occurs during pregnancy, antibiotics given promptly to the pregnant woman can often prevent infection of the fetus or newborn.
Babies with listeriosis receive the same antibiotics as adults, although a combination of antibiotics is often used until physicians are certain of the diagnosis. Even with prompt treatment, some infections result in death. *Vague symptoms as above described delay in iD cause death regardless of available treatment*
Government agencies and the food industry have taken steps to reduce contamination of food by the *Listeria* bacterium. The Food and Drug Administration and the U. S. Department of Agriculture monitor food regularly. When a processed food is found to be contaminated, food monitoring and plant inspection are intensified, and if necessary, the implicated food is recalled, but hard to dientify the user

Due to seousnes ad large number foodborne illnesses outbreaks caused by apple cider juice, advising the apple cider industry and the public of the potential risks associated with unpasteurized cider before the 1997 fall apple cider season. On August 28, 1997 FDA published a Federal Register Notice titled "Fruit and Vegetable Juice Beverages: Notice of Intent to Develop a HACCP Program, Interim Warning Statement, and Educational Program" (Vol. 62, No, 167, p 45593–45596). The notice announced measures to reduce the risk of illness from disease-causing microorganisms in unpasteurized fruit and vegetable juices. . In addition, consumers should be educated about the risks to certain populations associated with the consumption of untreated juice and the potential for the presence of pathogens and other hazardous substances.
Actions to prevent the occurrence and avoid the spread of disease due to lack of idebtification and location of the harmful product or contaminated individual is critical fo rthe cointainment of the acceleration in health care spending FDA believed there was an urgency in

Animal Health Products. DMC is responsible for monitoring the feeds eaten by animals and the safety of the food produced from animals. The focus of CVM's efforts is on feeds for livestock or poultry that ultimately become or produce foods for humans. In cooperation with the USDA and

EPA, the FDA has developed a Contamination Response System (CRS) designed primarily to prevent interstate movement of contaminated feed.

Escherichia coli O157:H7 bacteria were first recognized as a cause of human disease in 1982. Other types of toxin-producing *E. coli*, such as *E. coli* O111, can cause similar illness and are spread in the same way, but are less common. Large outbreaks of *E. coli* O157:H7 have been reported in the United States, including an outbreak in 1993 linked to undercooked hamburgers that resulted in more than 600 reported cases and 4 deaths. In 1996, more than 6000 schoolchildren in Japan developed *E. coli* O157:H7 infection from eating contaminated radish sprouts.
E. coli O157:H7 infection typically begins with severe abdominal cramps and non-bloody diarrhea. Vomiting occurs in about half of persons with *E. coli* infection. Fever, usually not high, occurs less than one-third of the time. On the second or third day of illness, stools may become bloody in 30% to 75% of cases
The infection OCCURS AND spread through contaminated food, such as beef , milk, unpasteurized apple juice, cider, sprouts, and other fruits and vegetables, Person-to-person transmission of *E. coli* O157:H7 may also occur and can play an important role in spread among family members, in day-care settings, or in institutions.
Contamination of meat may occur during slaughter when bacteria from the animal's intestines contaminate the surface of the meat. Manure also contains the bacteria and can contaminate meat or other foods.
To prevent spread from infected persons, locating the source is essential.

Hepatitis A (formerly known as infectious hepatitis) is a liver disease caused by the hepatitis A virus it can be spread by consuming either water, or undercooked shellfish contaminated with improperly treated sewage. The hepatitis A virus enters through the mouth, multiplies in the body and is passed in the feces. The virus can then be carried on an infected person's hands and can be spread by direct contact, or by consuming food or drink that has been handled by the individual.
DMC help. Locating to avoid spread

About **3,000 products** a year are found to be unfit for consumers and are withdrawn from the marketplace BY THE fda ALONE, either by voluntary recall or by court-ordered seizure.

periodic health checkups, NOW CAN BE DONE AT HOME WITH THE DEVICES BY ABREU

CLAIMS

A method to be utilized by a user of a product, said method comprising the steps of:

Acquiring data on a product that uniquely identified said product
Storing in the memory of a computer said product identification data including information indicative of unique identification of the user of said product
Acquiring or receiving from entities information related to products
Storing said acquired or received information in the memory of a computer including means to connect to said entities
Searching said computer memory for products which matches the information acquired or received from said entities
Transmitting to said user the information related to said products stored under said user name

A computer (or microprocessor-based) (or article of manufacturing) device comprising -portable

Means to enter product identifiers
Means for executing a program to generate an alert according to said product identifier entered
Means to communicate with a central computer
Means for transmitting said alert message to a central computer
Means for receiving instructions corresponding to said alert

A computer (or microprocessor-based) device comprising -portable

Means to enter product identifiers
Means to store product identifiers
Means to store recall and warning information
Means for executing a program to generate an alert according to said product identifiers entered
Means to provide said alert to a user

A computer device comprising -portable

Means to enter product identifiers
Means to connect to a central computer
Means to transmit said data on entered products
Means for receiving information from the central computer related to entered products
Means for providing said information to the user

A computer device (server) comprising of:

Means for registering a user of products
Means for storing product identifiers corresponding to a particular user
Means for receiving from entities information corresponding to products
Means for storing said information on products
Means for matching products and information
Means for generating messages corresponding to said product and information matching
Means for transmitting said message to a user

Article of manufacture
Computer readble medium
Computer readbale programs for obtainng data

Method

PAREI AQUI 8-1-99

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: ABREU

Atty. Docket No.: P66081US1

Serial No.: 09/778,762

Group Art Unit: 3626

Filed: February 8, 2001

Examiner: Lena Najarian

For: SYSTEM AND METHOD FOR COMMUNICATING PRODUCT RECALL INFORMATION, PRODUCT WARNINGS OR OTHER PRODUCT-RELATED INFORMATION TO USERS OF PRODUCTS

DECLARATION UNDER 37 C.F.R. §1.131

I, Craig W. Brock, hereby declare as follows:

1. I reside at 336 Park Avenue, West Mifflin, Pennsylvania, 15122.

2. I graduated from Worcester Polytechnic Institute in May, 1982 with a B.S. in Electrical Engineering.

3. From 1982 to 1984, I was employed as a software engineer with Hamilton Standard of Windsor Locks, Connecticut. At Hamilton Standard, I modified fuel controller source code to incorporate design changes.

4. From 1984 to 1990, I was employed as a software engineer with Honeywell Electro Optics of Lexington, Massachusetts. At Honeywell, I created software for a scanner system that allowed real-time viewing of imagery, I was involved in the

5. I was employed as a software engineer from 1991-2005 for Bechtel Bettis, Inc., West Mifflin, Pennsylvania. During this time frame, I assisted in the creation of software building blocks for use in Generic Instrument and Control Systems, have run test suites on the C++ compiler used for the U.S.S. Theodore Roosevelt's nuclear reactor, tested the performance of the RTD Generic hardware building block with all RTDs that it was designed to interface with, created a software simulation, running on a Motorola 68040 processor board, of the PSSI Generic hardware building block to allow software testing before prototype boards were available and performed software inspection of the PL/M code for Seawolf class submarines.

6. In 2006, I was employed as a software engineer for Union Switch and Signal. I performed unit testing of ATP software for the Los Angeles transit system.

7. During the time frame of early 1999, I became familiar with the work of Dr. Marc Abreu for the subject matter of the above-captioned application.

8. During the time frame of early to mid-1999, I received technical information

from Dr. Abreu. I was asked to review the operability of this information based on my technical expertise as a software engineer.

9. Attached is a copy of diagrams I was asked to review by Dr. Abreu in the May to June, 1999 time frame.

10. Dr. Abreu shared the attached information with me on a confidential basis. Based upon his work at the University of Pittsburgh Medical Center where Dr. Abreu had seen many serious injuries in the Emergency Room due to harmful or recalled products, Dr. Abreu explained that he had designed a computer-based automated location and notification system for recalled or harmful products.

11. Dr. Abreu asked me to review his recalled products warning system based on my current work at that time on computer code for submarines of the U.S. Navy.

12. I am aware of the time frame of May to June 1999 for having reviewed the attached documents because Dr. Abreu left the Pittsburgh area in July, 1999. I remember having received and reviewed the attached documents from Dr. Abreu shortly prior to his leaving the Pittsburgh area.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that the statements are made with the knowledge that willful false

thereon.

Craig W. Brock

May 8, 2007

JLS/kad